

(19) World Intellectual Property Organization  
International Bureau(43) International Publication Date  
15 August 2002 (15.08.2002)

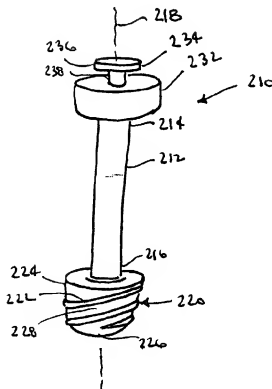
PCT

(10) International Publication Number  
WO 02/062234 A2

- (51) International Patent Classification: **A61B 17/00**
- (21) International Application Number: PCT/US01/48843
- (22) International Filing Date:  
11 December 2001 (11.12.2001)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
09/738,431 14 December 2000 (14.12.2000) US  
09/866,548 25 May 2001 (25.05.2001) US  
09/931,676 15 August 2001 (15.08.2001) US
- (71) Applicant: **INTEGRATED VASCULAR SYSTEMS, INC.** [US/US], 3259 Kifer Road, Santa Clara, CA 95051 (US).
- (72) Inventors: **GINN, Richard, S.**; 297 Marti Way, San Jose, CA 95136 (US). **SALMON, Stephen, M.**; 1177 Hagen Road, Napa, CA 94558 (US). **JABBA, Ronald, J.**; 144 Oakdale Street, Redwood City, CA 94062 (US).
- (74) Agent: **ENGLISH, William, A.**; Lyon & Lyon LLP, 633 West Fifth Street, 47th Floor, Los Angeles, CA 90071-2066 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.
- (84) Designated States (*regional*): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

[Continued on next page]

(54) Title: DEVICES FOR SEALING OPENINGS THROUGH TISSUE AND APPARATUS FOR DELIVERING THEM



(57) Abstract: An apparatus for sealing a passage through tissue includes an elongate shaft and a cylindrical plug disposed on a distal end of the shaft, the plug including a helical thread on its outer surface. Intestinal submucosa may be secured to the plug, e.g., in a cavity in its distal end, that may be delivered into the passage. Alternatively, the plug may be formed from a bioabsorbable material and may be released from the shaft within the passage. The plug is threaded into the passage, thereby engaging the tissue to seal the passage. The shaft is rotated until it engages a blood vessel within the tissue while monitoring blood flow through the vessel. The shaft is rotated to thread the plug into the passage until blood flow ceases through the vessel, whereupon rotation of the shaft is reversed to back the plug until blood flow through the vessel resumes.



**Published:**

*without international search report and to be republished  
upon receipt of that report*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

- 1 -

## DEVICES FOR SEALING OPENINGS THROUGH TISSUE AND APPARATUS FOR DELIVERING THEM

### 5                                    FIELD OF THE INVENTION

The present invention relates generally to systems and methods for sealing or closing passages through tissue, and more particularly to devices for sealing punctures or other openings communicating with body lumens, such as blood vessels, and to apparatus and methods for delivering such devices.

10

### BACKGROUND

Catheterization and interventional procedures, such as angioplasty or stenting, generally are performed by inserting a hollow needle through a patient's skin and muscle tissue into the vascular system. A guide wire may then be passed through the needle  
15 lumen into the patient's blood vessel accessed by the needle. The needle may be removed, and an introducer sheath may be advanced over the guide wire into the vessel, e.g., in conjunction with or subsequent to a dilator. A catheter or other device may then be advanced through a lumen of the introducer sheath and over the guide wire into a position for performing a medical procedure. Thus, the introducer sheath may facilitate  
20 introduction of various devices into the vessel, while minimizing trauma to the vessel wall and/or minimizing blood loss during a procedure.

Upon completion of the procedure, the devices and introducer sheath may be removed, leaving a puncture site in the vessel wall. External pressure may be applied to the puncture site until clotting and wound sealing occur. This procedure, however, may be  
25 time consuming and expensive, requiring as much as an hour of a physician's or nurse's time. It is also uncomfortable for the patient, and requires that the patient remain immobilized in the operating room, catheter lab, or holding area. In addition, a risk of hematoma exists from bleeding before hemostasis occurs.

Various apparatus have been suggested for percutaneously sealing a vascular  
30 puncture by occluding the puncture site. For example, U.S. Patent Nos. 5,192,302 and 5,222,974, issued to Kenney et al., describe the use of a biodegradable plug that may be delivered through an introducer sheath into a puncture site. When deployed, the plug may

- 2 -

seal the vessel and provide hemostasis. Such devices, however, may be difficult to position properly with respect to the vessel, which may be particularly significant since it is generally undesirable to expose the plug material, e.g., collagen, within the bloodstream, where it may float downstream and risk causing an embolism.

- 5 Another technique has been suggested that involves percutaneously suturing the puncture site, such as that disclosed in U.S. Patent No. 5,304,184, issued to Hathaway et al. Percutaneous suturing devices, however, may require significant skill by the user, and may be mechanically complex and expensive to manufacture.

- 10 Staples and surgical clips have also been suggested for closing wounds or other openings in tissue. For example, U.S. Patent Nos. 5,007,921 and 5,026,390, issued to Brown, disclose staples that may be used to close a wound or incision. In one embodiment, an "S" shaped staple is disclosed that includes barbs that may be engaged into tissue on either side of the wound. In another embodiment, a ring-shaped staple is disclosed that includes barbs that project from the ring. These staples, however, have a  
15 large cross-sectional profile and therefore may not be easy to deliver through a percutaneous site to close an opening in a vessel wall.

- In addition, skin seals have been proposed that may be threaded into an opening in skin. For example, U.S. Patent No. 5,645,565, issued to Rudd et al., discloses a surgical plug that may be screwed into a puncture to seal the puncture. The surgical plug includes  
20 an enlarged cap and a threaded shaft that extends from the cap. During an endoscopic procedure, the plug may be threaded into an opening through skin until the cap engages the surface of the skin. The plug is intended to seal the opening communicating with a body cavity to prevent insufflation fluid from leaking from the cavity. Such plugs, however, may only be used at the surface of the skin, and may not be introduced through  
25 tissue, for example, to seal an opening in the wall of a blood vessel or other subcutaneous region.

Accordingly, devices for sealing punctures or other passages through tissue, e.g., an opening into a blood vessel, would be considered useful.

### SUMMARY OF THE INVENTION

The present invention is directed to systems and methods for sealing or closing passages through tissue, such as punctures communicating with blood vessels or other body lumens.

5        In accordance with one aspect of the present invention, an apparatus for sealing a passage through tissue is provided that includes an elongate member having a proximal end and a distal end, and a generally cylindrical plug member disposed on the distal end of the elongate member, the plug member including an outer surface having a helical thread thereon.

10        In one embodiment, the plug member includes a cavity in its distal end. A hemostasis-promoting material, such as intestinal submucosa, or an infection-resistant material, may be disposed in the cavity or otherwise secured to the plug member. The material may be delivered into the passage to facilitate hemostasis and/or healing of tissue proximate the passage. Alternatively, a lumen may be provided that extends from the  
15        proximal end of the elongate member through the plug member, and a seal may be provided for selectively sealing the lumen. The lumen may facilitate insertion of the apparatus and/or may facilitate monitoring hemostasis within the tissue.

      In another embodiment, the plug member is releasable from the elongate member. Preferably, the plug member is formed from a bioabsorbable material such that the plug  
20        member may be released within the tissue to seal the passage, and allowed to be absorbed by the tissue over time. The elongate member preferably includes an actuator for releasing the plug member from the distal end of the elongate member. Preferably, cooperating connectors are provided on the distal end of the elongate member and the plug member for releasably securing the plug member to the distal end of the elongate member.  
25        Alternatively, the elongate member may include an expandable member, such as a frame, on its distal end that may be selectively expanded to engage an interior wall of the plug member and collapsed to release the plug member.

      In accordance with another aspect of the present invention, a method is provided for sealing a passage through tissue. An apparatus is provided that includes an elongate  
30        member and a generally cylindrical plug member disposed on a distal end of the elongate member, the plug member including an outer surface having a helical thread thereon.

- 4 -

The plug member is inserted into the passage, and the elongate member is rotated, thereby threading the plug member within the passage, the plug member engaging the tissue to substantially seal the passage. In one preferred method, the passage communicates with a blood vessel within the tissue, and the elongate member is rotated until the plug member substantially seals a wall of the blood vessel. The plug member may be left within the passage for sufficient time for hemostasis to occur, whereupon the plug member may be removed from the passage. In addition or alternatively, a hemostasis-promoting material may be provided within a cavity in a distal end of the plug member, and the material may be left in the passage when the plug member is removed.

In a further alternative, the plug member itself may be released from the elongate member within the passage. Preferably, in this embodiment, the plug member is formed from a bioabsorbable material.

In another preferred embodiment, the elongate member is rotated until it engages a blood vessel within the tissue. Blood flow at a location downstream of the blood vessel may be monitored, e.g., by feeling the patient's pulse. The elongate member may be rotated in a first direction to thread the plug member deeper into the passage until blood flow substantially ceases downstream of the blood vessel. Rotation of the elongate member may then be reversed to back the plug member a predetermined distance, thereby allowing blood flow to resume downstream of the blood vessel. The plug member may be released at this location or otherwise maintained at this location until hemostasis and/or healing occurs.

In accordance with yet another aspect of the present invention, an apparatus is provided for sealing a passage through tissue that includes an elongate guide member, a carrier member, and a plug member. The guide member includes a groove in an outer wall of the guide member that extends between proximal and distal portions of the guide member. The carrier member includes proximal and distal ends, and a first lumen extending between the proximal and distal ends.

A plug member, e.g., formed from bioabsorbable material, may be carried on the distal end of the carrier member. The plug member may be releasable from the distal end of the carrier member, e.g., by cooperating connectors, and/or an actuator, or may be substantially permanently attached to the carrier member. The plug member includes a second lumen extending therethrough that communicates with the first lumen, and may

include a sealing member disposed in the second lumen for substantially sealing the second lumen from fluid flow therethrough. The plug member may include a substantially smooth outer surface, or may include a helical thread on its outer surface. Preferably, the plug member has a cross-section larger than a cross-section of the carrier member, e.g., to minimize dilation of a passage through which the carrier member is inserted.

The guide member is slidable into the first and second lumens such that edges of the groove substantially engage walls of the first and second lumens to define a bleed back lumen.

In accordance with still another aspect of the present invention, a method is provided for sealing a passage through tissue communicating with a body lumen, e.g., a puncture communicating with a blood vessel. The passage may be used to access the body lumen, e.g., to perform an endovascular procedure within the patient's body. Upon completion of the procedure, any instruments received through the passage may be removed, although an introducer sheath and/or guidewire may remain in place through the passage into the vessel.

An elongate member including a groove extending between its proximal and distal portions may be inserted into the passage, e.g., through the introducer sheath or over the guidewire, until the distal portion enters the body lumen. The introducer sheath may be removed (if used), and a plug member disposed on a carrier member may be advanced over the elongate member with the elongate member received in a lumen of the plug member such that the groove and the lumen together define a bleed back lumen. The plug member may include an external thread, and consequently the carrier member may be rotated to thread the plug member into the passage.

When the plug member enters the body lumen, fluid from the body lumen may enter the bleed back lumen to identify the location of the body lumen with respect to the plug member. In one embodiment, a first fluid flow rate through the groove may be detected when the distal portion of the elongate member initially enters the body lumen (before insertion of the plug member and carrier member), and a second greater fluid flow rate through the bleed back lumen may be detected when the plug member begins to enter the body lumen.

The plug member may be released from the carrier member within the passage, and the carrier member and/or guide member may be removed from the plug member.

The plug member may include a sealing member for sealing the lumen upon removal of the guide member. Preferably, the plug member is formed at least partially from bioabsorbable material, and is left within the passage until it is absorbed by the tissue.

- In accordance with yet another aspect of the present invention, an apparatus is
- 5 provided for sealing a passage through tissue communicating with a body lumen. The apparatus includes a plug member including a distal end and a proximal end. The plug member may include a tapered portion terminating in the distal end, and a helical thread pattern on an outer surface of the plug member. The plug member may also include a lumen extending from the proximal end to a location proximal to the distal end.
- 10 The plug member may be continuously tapered from the proximal end to the distal end, preferably having a frustoconical shape, defining substantially blunt distal end. The lumen may communicate with a distal port that may be disposed on the distal end or offset proximally from the distal end by a predetermined distance.

- The apparatus may also include a carrier member or handle device including
- 15 proximal and distal ends, the plug member being coupled to the distal end of the carrier member. The carrier member may include a lumen extending between the proximal and distal ends that communicates with the lumen in the plug member. The plug member may be formed from bioabsorbable material, and/or may be releasable from the distal end of the carrier member, similar to the embodiment described above.

- 20 In accordance with another aspect of the present invention, a device for sealing a passage through tissue is provided that includes a body, e.g., formed from bioabsorbable material, including a proximal end, a distal end, and a helical thread on an outer surface extending at least partially between the proximal and distal ends. The body includes a lumen extending between the proximal end and a distal inlet port. A sealing member is
- 25 disposed within the lumen that is expandable for substantially sealing the lumen from fluid flow therethrough.

- In one embodiment, the sealing member includes a material that is expandable when exposed to fluid to substantially seal the lumen, such as a foam and/or a bioabsorbable material. The sealing member may be a valve or other device that is biased
- 30 towards a first configuration for substantially sealing the lumen from fluid flow therethrough, and is movable to a second configuration for accommodating introduction of one or more devices through the lumen.



- 7 -

In another embodiment, the lumen includes a tapered portion that tapers in cross-section, and the sealing member is a generally annular-shaped member disposed adjacent a wide end of the tapered portion of the lumen. The sealing member is movable into the tapered portion for substantially sealing the lumen from fluid flow therethrough.

5 In accordance with yet another aspect of the present invention, an apparatus is provided for sealing a passage through tissue that includes a handle device or other elongate member and a plug member. The elongate member has a proximal end, a distal end, and a lumen extending between the proximal and distal ends. The plug member is disposed on the distal end of the elongate member, and includes a helical thread on its  
10 outer surface and a distal port therein in communication with the lumen.

Preferably, the plug member includes a passage therein extending between the distal port and the lumen. A sealing member may be disposed in the passage for substantially sealing the passage from fluid flow therethrough, such as that described above. In one embodiment, the passage and lumen define a bleed back lumen for  
15 determining the location of the plug member relative to a blood vessel or other body lumen.

In another embodiment, an obturator or other elongate member is insertable through the lumen such that a distal end of the obturator is disposed beyond the distal end of the plug member. The obturator may include a location indicator for identifying when  
20 the distal end of the plug member is disposed adjacent a body lumen. The location indicator may include a bleed back lumen in the obturator and a bleed back port on its distal tip, the bleed back port being in communication with the bleed back lumen. Alternatively, the location identifier may include an expandable member on a distal tip of the obturator, the expandable member being expandable when the distal tip is disposed  
25 within a body lumen for providing tactile feedback of a location of the distal end of the plug member with respect to the body lumen.

Preferably, the plug member is releasable from the elongate member. The elongate member may include an actuator for releasing the plug member from the distal end of the elongate member. Preferably, cooperating connectors are provided on the distal end of the  
30 elongate member and on the plug member for releasably securing the plug member to the distal end of the elongate member.

In accordance with still another aspect of the present invention, a method is provided for sealing a passage through tissue communicating with a body lumen using an apparatus, such as that described above. Generally, the apparatus includes an elongate member, and a plug member disposed on a distal end of the elongate member. The plug member includes an outer surface including a helical thread, and a bleed back indicator associated with a distal end of the plug member.

The plug member is inserted into the passage until the helical thread begins to enter the passage. The elongate member may be rotated in a first direction, thereby threading the plug member into the passage until the bleed back indicator enters the body lumen, whereupon fluid from the body lumen may enter the bleed back indicator to identify the location of the body lumen with respect to the plug member. If desired, rotation of the elongate member may be reversed, thereby withdrawing the plug member a predetermined distance relative to the body lumen. Thereafter, the plug member may be released from the elongate member within the passage. Preferably, the plug member is formed from bioabsorbable material, and the plug member is left within the passage until it is absorbed by the tissue.

In a preferred embodiment, the elongate member includes a lumen extending from its proximal end through the plug member, and the bleed back indicator includes a bleed back port in the plug member, the bleed back port being in communication with the lumen. Alternatively, an obturator may be inserted through the lumen until a distal end of the obturator extends distally beyond the plug member, and the bleed back indicator may include a bleed back lumen in the obturator.

A sealing member may be provided in a lumen of the plug member for sealing the lumen, and consequently the bleed back port, from fluid flow therethrough. The sealing member may be an expandable material that expands when exposed to fluid. Alternatively, the sealing member may be a generally annular-shaped element that may be disposed adjacent a wide end of a tapered portion of the lumen. The annular-shaped may be moved or otherwise wedged into the tapered portion for substantially sealing the lumen.

Other objects and features of the present invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a first preferred embodiment of an apparatus for sealing a passage through tissue, in accordance with the present invention.

FIG. 2 is a cross-sectional side view showing a plug member on the apparatus of

- 5 FIG. 1 being used to deliver a patch to seal an opening in a wall of a blood vessel.

FIG. 3 is a perspective view of an alternative embodiment of an apparatus for sealing a passage through tissue, in accordance with the present invention.

FIG. 4 is a perspective view of a second preferred embodiment, including a detachable plug, in accordance with the present invention.

- 10 FIGS. 5A-5C are cross-sectional views of the apparatus of FIG. 4 being used to deliver the plug into a passage communicating with a blood vessel.

FIGS. 6A and 6B are cross-sectional views of another detachable plug and a delivery apparatus including an expandable frame shown in expanded and collapsed states, respectively, for securing and releasing the plug member.

- 15 FIG. 7A is an exploded perspective view of another preferred embodiment of an apparatus for sealing a passage through tissue, in accordance with the present invention.

FIG. 7B is a perspective view of the assembled apparatus of FIG. 7A.

FIG. 8A is a detail of a plug member on a distal end of the apparatus of FIGS. 7A and 7B.

- 20 FIG. 8B is a detail of an alternative embodiment of a plug member on a distal end of the apparatus of FIGS. 7A and 7B.

FIG. 9A is a cross-sectional view of the apparatus of FIG. 7B taken along line 9A-9A.

- 25 FIGS. 9B-9F are cross-sectional views of the apparatus of FIG. 7B, showing alternate embodiments of a guide member.

FIGS. 10A-10D are cross-sectional views showing a plug member on the apparatus of FIGS. 8A and 8B being used to seal an opening in a wall of a blood vessel.

FIGS. 11A and 11B are cross-sectional views of a distal end of a third preferred embodiment of a plug member, in accordance with the present invention.

- 30 FIGS. 12 is an exploded perspective view of a fourth preferred embodiment of an apparatus for sealing a passage through tissue, in accordance with the present invention.

- 10 -

FIGS. 13A and 13B are cross-sectional views showing a plug member on the apparatus of FIG. 12 being used to seal an opening in a wall of a blood vessel.

FIG. 14A is an exploded perspective view of a fifth preferred embodiment of an apparatus for sealing a passage through tissue, in accordance with the present invention.

5 FIG. 14B is a perspective view of the assembled apparatus of FIG. 14A.

FIG. 15 is a detail of a distal end of the apparatus of FIGS. 14A and 14B.

FIGS. 16A-16D are cross-sectional views showing a plug member on the apparatus of FIGS. 14A and 14B being used to seal an opening in a wall of a blood vessel.

10 FIGS. 17A is an exploded perspective view of a sixth preferred embodiment of an apparatus for sealing a passage through tissue, in accordance with the present invention.

FIG. 17B is a perspective view of the assembled apparatus of FIG. 17A.

FIG. 18 is a side view of a seventh preferred embodiment of an apparatus for sealing a passage through tissue, in accordance with the present invention.

15 FIG. 19A is a cross-sectional side view of an eighth preferred embodiment of an apparatus for sealing a passage through tissue, including a plug member with a sealing member within its lumen, in accordance with the present invention.

FIG. 19B is a cross-sectional detail of the plug member of FIG. 19A, taken along line 19B-19B, showing the sealing member in an open configuration.

20 FIG. 19C is a cross-sectional side view of the apparatus of FIG. 19A, with the sealing member wedged into a tapered portion of the lumen.

FIG. 19D is a cross-sectional detail of the plug member of FIG. 19C, taken along line 19D-19D, showing the sealing member wedged into a closed configuration.

FIGS. 20A-20F are cross-sectional views showing an apparatus and method for delivering a plug member to seal a puncture communicating with a blood vessel.

25

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning now to the drawings, FIG. 1 shows a first preferred embodiment of an apparatus 10 for sealing a passage through tissue, in accordance with the present invention. Generally, the apparatus 10 includes an elongate shaft 12 and a plug member 20. The shaft 12 has a proximal end 14 and a distal end 16 defining a longitudinal axis 18 therebetween. A handle 32 may be provided on the proximal end 14 of the shaft 12 for

- 11 -

facilitating manipulation of the apparatus 10, e.g., to facilitate rotation of the apparatus 10 into a passage, as described below.

The plug member 20 is disposed on the distal end 16 of the shaft 12 and includes a helical thread 22 extending at least partially between its proximal and distal ends 24, 26.

- 5 The plug member 20 is a substantially rigid body having a generally cylindrical shape and defining an outer surface 28 along which the helical thread 22 extends. The helical thread 22 preferably is substantially rigid and has a substantially square cross-section to facilitate sealing of a passage into which the plug member 20 is threaded. Alternatively, the plug member 20 may be a semi-rigid or flexible body or may have a substantially flexible distal tip (not shown), e.g., to facilitate atraumatic insertion of the plug member 20 into the passage.

- 15 Preferably, the shaft 12 has a cross-section that is substantially smaller than a cross-section of the plug member 20, e.g., to minimize dilation of a passage into which the apparatus 10 is inserted. The plug member 20 may be tapered between the proximal and distal ends 24, 26 and/or the distal end 26, or only partially tapered, e.g., at the distal end 26. In addition or alternatively, the distal end 26 may be rounded to facilitate advancement of the plug member 20 into a passage through tissue.

- 20 In a preferred embodiment, the helical thread 22 is integrally formed on the outer surface 28 of the plug member 20. For example, the plug member 20 and thread 22 may be formed by injection molding. Alternatively, the threads may be cut or otherwise formed in the outer surface 28 of the plug member 20. The plug member 20 may be formed from a biocompatible material, preferably a plastic, such as polyethylene or polyester. The plug member 20 may be substantially permanently attached to the distal end 16 of the shaft 12, for example, by mechanical detents and/or an adhesive.
- 25 Alternatively, the shaft 12 and plug member 20 may also be integrally formed as a single piece. In a further alternative, the plug member 20 may releasably attached to the shaft 12, as described below.

- In one embodiment, the plug member 20 includes a cavity, such as concave recess 30, in its distal end 26. A material (not shown) may be provided in the cavity 30, such as intestinal submucosa, collagen, an infection-resistant material, and the like. Such material may promote hemostasis and/or healing of the tissue, as will be appreciated by those skilled in the art. Alternatively, the material may be otherwise detachably secured to the

distal end 26 of the plug member 20, either within the cavity 30 or across the distal end 26 without a cavity (not shown). For example, the material may be secured using a biodegradable adhesive or a mechanical fastener, such as one or more clips (not shown). Such a fastener may be actuated from the proximal end 14 of the shaft 12 to release the material, or the material may otherwise be automatically released upon withdrawal of the plug member 20.

Turning to FIG. 2, during use, the plug member 20 may be used to seal and/or close a passage through tissue 96, such as a puncture 92 communicating with a blood vessel 90 or other body lumen. The puncture 92 may be used to provide percutaneous access to the blood vessel 90. For example, the puncture 92 may facilitate performing an endovascular procedure within a patient's vasculature, such as angioplasty, stenting, atherectomy, and the like, or may otherwise provide access via the blood vessel 90 to a region within the patient's body. Upon completion of the procedure, any instruments, such as an introducer sheath (not shown), may be removed from the blood vessel 90 and puncture 92.

The apparatus 10 may then be introduced into the puncture 92, for example, by at least partially inserting the plug member 20 into the puncture 92. Preferably, the outer surface 28 and threads 22 engage tissue 96 surrounding the puncture 92, thereby substantially sealing the puncture 92 from fluids, such as blood, within the vessel 90. The apparatus 10 may then be rotated in a first direction about its longitudinal axis 18 to thread the plug member 20 substantially atraumatically deeper into the puncture 92. Preferably, the plug member 20 is advanced until its distal end 26 is proximate to the wall 98 of the vessel 90.

In the embodiment shown in FIG. 2, a patch 40, e.g., of intestinal submucosa or other hemostasis-promoting material, is provided in a cavity 30 within the distal end 26 of the plug member 20. For example, U.S. Patent No. 2,167,251, issued to Rogers, discloses exemplary materials that may be included in the cavity 30 or otherwise detachably secured to the plug member 20. The disclosure of this reference and any others cited therein are expressly incorporated herein by reference.

When the plug member 20 is advanced proximate the wall 98 of the vessel 90, the patch 40 is delivered within or adjacent to the wall 98. The patch 40 may promote hemostasis and/or healing of the wall 98 at the puncture site. After hemostasis and/or a

- 13 -

desired level of healing has occurred, the plug member 20 may be withdrawn from the puncture 92 by rotating the apparatus 10 in a second direction opposite the first direction. Alternatively, the patch 40 may be delivered to the wall 98 at the puncture site simply by releasably securing the patch 40 to the distal end 26 of the plug member 20, as described  
5 above. Alternatively, the plug member 20 may be advanced into the puncture 92 without a patch to seal the puncture and allow hemostasis and/or healing to occur naturally before removal of the plug member 20.

Turning to FIG. 3, another embodiment of an apparatus 110 is shown for sealing a passage through tissue. Similar to the previous embodiment, the apparatus 110 includes  
10 an elongate shaft 112, a plug member 120 disposed on a distal end 116 of the shaft 112, and a handle 132 on a proximal end 114 of the shaft 112. In addition, the apparatus 110 includes a lumen 136 extending from the proximal end 114 of the shaft 112 distally through the plug member 120. A seal 138, such as a hinged cap, may be provided for sealing an opening 140 communicating with the lumen 138. The seal 138 and opening  
15 140 may be provided on the handle 132 or elsewhere on the proximal end 114 of the shaft 112.

Use of the apparatus 110 is similar to the previous embodiment, i.e., the plug member 120 is threaded into a puncture, e.g., to seal an opening in a wall of a blood vessel (not shown). The seal 138 is initially provided closed, thereby preventing blood or other  
20 fluid from passing through the lumen 136 to the proximal end 114 of the shaft 112. Alternatively, the cap 138 may be initially provided open, such that when the distal end 126 of the plug member 120 starts to enter a blood vessel, blood within the vessel may enter and pass proximally through the lumen and exit the opening 140, thereby providing a visual indicator that the plug member 120 has reached the vessel. The seal 138 may then  
25 be sealed to prevent further flow of fluid therethrough.

Periodically, the seal 138 may be opened to see if fluid flows from within the vessel through the lumen 136. Once hemostasis occurs, such flow may no longer occur when the seal 138 is opened, thereby indicating that the apparatus 110 may be removed. Alternatively, the lumen 136 may be coupled to another tube or other external system that  
30 may facilitate monitoring of fluid flow through the lumen 136.

Turning to FIG. 4, another preferred embodiment of an apparatus 210 is shown for sealing a passage through tissue. Similar to the previous embodiments, the apparatus 210

includes an elongate shaft 212, a plug member 220 disposed on a distal end 216 of the shaft 212, and a handle 232 on a proximal end 214 of the shaft 212. Unlike the previous embodiment, however, the plug member 220 is releasable from the shaft 212. The plug member 220 preferably is at least partially formed from bioabsorbable material, such as collagen, PGA's, PLA's, and the like, that may be at least partially absorbed by the patient's body over time.

The plug member 220 and the distal end 216 of the shaft 212 generally include cooperating connectors (not shown) for releasably securing the plug member 220 to the shaft 212. For example, the plug member 220 may include a recess (not shown) in its proximal end 224 and the shaft 212 may include a mechanism, e.g., radially projecting fingers, for frictionally engaging the wall of the recess. Alternatively, the recess may include slots for positively receiving the mechanism on the shaft 212. In a further alternative, the plug member 220 may include a hub (not shown) extending from its proximal end 224 and the shaft 212 may include a mechanism for detachable securing the hub to the shaft 212.

Preferably, the handle 232 includes an actuator 234 that may be activated to release the connectors securing the plug member 220 to the shaft 212. For example, the actuator 234 may include a button 236 coupled to a control rod or wire 238 that extends through the shaft 212 to its distal end 216. Upon depression of the button 236, the control rod 238 may be moved, thereby disengaging the connector on the shaft 212 from the mating connector on the plug member 220. In another alternative, the distal end 216 of the shaft 212 and the plug member 220 may include mating threads (not shown) so that the shaft 212 may be rotated with respect to the plug member 220 to release the plug member 220. In this embodiment, the mating threads should wind helically in the same direction as the helical threads 224 to ensure that the plug member 220 is not released prematurely from the shaft 212.

Turning to FIGS. 5A-5C, the apparatus 210 may be used to seal a passage 92 extending from a patient's skin 94 through tissue 96 to a blood vessel 90 or other body lumen. The passage 92 may be formed, a procedure performed within the patient's body via the vessel 90, and any instruments removed from the passage 92. The plug member 220 may be introduced into the passage 92, and the apparatus 210 may be rotated to thread the plug member 220 into the passage 92. Preferably, the threads 222 facilitate controlled



- 15 -

advancement of the plug member 220 through the tissue 94 and/or facilitate substantially sealing of fluid flow through the passage 92.

Preferably, while advancing the plug member 220, blood flow at a location downstream of the blood vessel 90 is monitored. For example, the patient's pulse may be manually or automatically monitored downstream of the puncture site. The apparatus 210 may be rotated, advancing the plug member 220 until blood flow substantially ceases downstream of the blood vessel. This may indicate that the plug member 220 has engaged and compressed the blood vessel 90, as shown in FIG. 5A.

Rotation of the apparatus 210 may then be reversed to back the plug member 220 a predetermined distance, thereby allowing blood flow to resume downstream of the blood vessel 90. For example, the threads 222 may have a predetermined thread spacing such that the apparatus 210 may be rotated a predetermined number of times to accurately withdraw the plug member 220 from compressing the blood vessel 90 while still substantially sealing the passage 92 at the wall 98 of the vessel 90, as shown in FIG. 5B.

The plug member 220 may then be released from the shaft 212, e.g., by depressing the actuator 234, and the shaft 212 withdrawn from the passage 92, leaving the plug member 220 within the passage 92, as shown in FIG. 5C. Because the plug member 220 is bioabsorbable, the plug member 220 may be absorbed by the tissue over time, thereby allowing the wall 98 of the vessel 90 and tissue 96 surrounding the passage 92 to at least partially heal before the plug member 220 is absorbed.

In an alternative embodiment, the plug member 220 may be biocompatible, but not bioabsorbable. In this alternative, it may be desirable or necessary to subsequently remove the plug member 220, e.g., once hemostasis and/or healing of the wall 98 of the vessel 90 has occurred. The plug member 220 may be retrieved by creating an incision in the patient's skin 94 and/or through the tissue 96 (e.g., if the passage has healed), and introducing an apparatus (not shown) to retrieve the plug member 220, such as a shaft having a connector on its end, similar to the apparatus 210 used to deliver the plug member 220.

Turning to FIGS. 6A and 6B, yet another preferred embodiment of an apparatus 310 is shown for sealing a passage through tissue. Similar to the previous embodiments, the apparatus 310 includes an elongate shaft 312, a plug member 320 disposed on a distal

- 16 -

end 316 of the shaft 312, and a handle (not shown) on a proximal end (also not shown) of the shaft 312.

5 The plug member 320 is preferably at least partially formed from bioabsorbable material that may be absorbed by the patient's body over time, similar to the embodiment described previously. The plug member 320 includes proximal and distal ends 322, 324 and a helical thread 326 extending along an exterior surface 328 thereof. In addition, an opening 330 in the proximal end 322 communicates with an interior cavity 332 defined by an interior wall 334.

10 An expandable member 336 extends from the distal end 316 of the shaft 312 for securing the plug member 320 to the shaft 312 during delivery. In a preferred embodiment, the expandable member 336 is a mechanically expandable frame including a plurality of radially movable arms 338. Preferably, the handle on the shaft 312 includes an actuator (not shown) that may be activated to control an actuator rod or wire 340, to selectively collapse and/or expand the frame 336 to release or secure the plug member 320  
15 to the shaft 312, respectively.

The frame 336 may be collapsed and inserted through the opening 330 into the interior cavity 332 of the plug member 320. The frame 336 may then be expanded to an expanded state, shown in FIG. 6A, to engage the interior wall 334 of the plug member 320, thereby substantially securing the plug member 320 to the distal end 316 of the shaft  
20 312. Subsequently, the frame 336 may be selectively collapsed to a collapsed state, shown in FIG. 6B, for releasing the plug member 320 from the shaft 312. In the collapsed state, the frame 336 may provided a relatively low cross-section or profile, thereby facilitating removal of the shaft 312 from a passage within which the plug member 320 is delivered.

In the expanded state, the radial arms 338 of the frame 336 may engage the interior  
25 wall 334 of the plug member 320 at a plurality of discrete locations. In this form, the plug member 320 is preferably sufficiently rigid that it is self-supporting when the frame 336 is collapsed. Alternatively, the radial arms 332 may support elongate bands (not shown), e.g., that extend between respective arms 322 that may provide greater surface contact with the interior wall 334 of the plug member 320. These bands may extend  
30 circumferentially and/or axially between arms 338 of the frame 336. Thus, the frame 336 may provide structural support for the plug member 320, e.g., during advancement of the apparatus 310 into a passage through tissue (not shown).

In an alternative embodiment, the expandable member may be an inflatable member (not shown), such as an elastic or inelastic balloon. Preferably, the balloon is substantially inelastic such that, when the balloon is fully expanded, it has a shape similar to the shape of the interior cavity 332 within the plug member 320. The balloon may engage the interior wall 334 of the plug member 320 to substantially support the plug member 320 during delivery. The balloon may be selectively inflated or deflated to secure the plug member 320 on the shaft 312 or to release the plug member 320 from the shaft 312, respectively.

The plug member 320 may be delivered to seal a passage through tissue, for example, using the method described above. The expandable member 330 (whether mechanical or inflatable) may be expanded to secure the plug member 320 on the shaft 312. The plug member 320 may be introduced into a passage, and the apparatus 310 may be rotated to thread the plug member 320 into the passage. Once advanced to a desired location, the plug member 320 may be released from the shaft 312, e.g., by collapsing the expandable member 330. The shaft 312 may then be withdrawn from the passage, leaving the plug member 320 within the passage.

Turning to FIGS. 7A and 7B, another preferred embodiment of an apparatus 410 for sealing a passage through tissue, in accordance with the present invention. Generally, the apparatus 410 includes a plug member 412, an elongate shaft or carrier member 414, and an elongate guide member 416.

The plug member 412 is a substantially rigid body, preferably having a generally cylindrical shape, including a proximal end 420, a distal end 422, and an outer surface 430. The plug member 412 includes a lumen 424 that extends between a proximal opening 426 and a distal opening or port 428.

The plug member 412 may be formed from a biocompatible material, e.g., a plastic, such as polyethylene or polyester. Preferably, the plug member 412 is formed at least partially (and more preferably entirely) from bioabsorbable material, such as collagen, polyglycolic acids (PGA's), polylactides (PLA's), and the like, that may be at least partially absorbed by the patient's body over time. Alternatively, the plug member 412 may be a semi-rigid or flexible body or may have a substantially flexible distal tip (not shown), e.g., to facilitate atraumatic insertion of the plug member 412 into the passage. In addition or alternatively, the plug member 412 may be tapered along its

length, and/or the distal end 422 may be rounded to facilitate advancement of the plug member 412 into a passage through tissue.

Preferably, the plug member 412 has a length of not more than about ten millimeters (10 mm), and more preferably between about one and ten millimeters (1-10 mm). The plug member 412 also preferably has a diameter of between about one and twenty millimeters (1-20 mm). In addition, the length and diameter may have a ratio that is not more than about two-to-one.

In one embodiment, shown in FIG. 8A, the outer surface 430 is substantially smooth, thereby facilitating direct advancement of the plug member 412 into a passage through tissue (not shown). In an alternative embodiment, shown in FIG. 8B, the plug member 412' may include a helical thread pattern 418', including one or more helical threads, that extend at least partially between its proximal and distal ends 420', 422'. The thread pattern 418' may extend completely to the distal end 422' of the plug member 412', and may be tapered at the distal end 422' to facilitate introduction into a passage through tissue (not shown). Additional information on plug members including an external helical thread pattern may be found in application Serial Nos. 09/866,548, and 09/738,431, incorporated by reference above.

Returning to FIG. 8A (in which the carrier member 414 has been eliminated for convenience), a sealing member 432 may be provided within the lumen 424 for substantially sealing the lumen 424 from fluid flow therethrough. In a preferred embodiment, the sealing member 432 has an annular shape, and is mounted within an annular recess 433 in the lumen 424. The sealing member 432 is preferably formed from a material that expands when exposed to fluids, e.g., an expandable foam. More preferably, the sealing member 432 is also bioabsorbable, similar to the plug member 412 itself. Exemplary materials that may be appropriate for use in the sealing member 432 and/or for the plug member 412 are disclosed in U.S. Patent No. 6,224,630, the disclosure of which is expressly incorporated herein by reference. Alternatively, the sealing member 432 may be a valve (not shown) that is biased to substantially seal the lumen 424 from fluid flow, but may be opened to facilitate introduction of one or more devices, e.g., the obturator 416 therethrough, as described further below.

In addition or alternatively, the plug member 412 may include a cavity (not shown) in the distal end 422. A material (also not shown) may be provided in the cavity, such as

extra-cellular matrix material, e.g., intestinal, stomach, or bladder submucosa, collagen, an infection-resistant material, and the like, that may promote hemostasis and/or healing of the tissue. Alternatively, such material may be otherwise detachably secured to the distal end 422 of the plug member 412, either within a cavity or across the distal end 422 without a cavity. For example, the material may be secured using a biodegradable adhesive or a mechanical fastener, such as one or more clips (not shown).

Returning to FIGS. 7A and 7B, the carrier member 414 has a proximal end 434 and a distal end 436, and defines a longitudinal axis 438 that extends between the proximal and distal ends 434, 436. A lumen 440 also extends between the proximal and distal ends 434, 436 for accommodating insertion of the guide member 416 therethrough, as described further below. A handle 442 may be provided on the proximal end 434 of the carrier member 414 for facilitating manipulation of the apparatus 410.

Preferably, the carrier member 414 is a substantially rigid tubular member, formed from a biocompatible material, e.g., plastic, such as polyethylene or polyester, or metal, such as stainless steel. The carrier member 414 preferably has a cross-section that is substantially smaller than a cross-section of the plug member 412, e.g., to minimize dilation of a passage into which the apparatus 410 is inserted. In the preferred embodiment shown, the carrier member 414 may include a lateral proximal portion 452 through which the lumen 440 extends and communicates with a proximal port 454. The proximal port 454 may be connected to a valve or other device (not shown) for facilitating visual observation of fluid exiting the proximal port 454, as will be appreciated by those skilled in the art.

At least one of the plug member 412 and the distal end 436 of the carrier member 414 includes a connector. Preferably, the plug member 412 and the distal end 436 of the carrier member 414 include cooperating connectors (not shown) for releasably securing the plug member 412 to the carrier member 414, as described in application Serial No. 09/738,431, incorporated above. Preferably, the cooperating connectors substantially couple the plug member 412 to the carrier member 414 such that the plug member 412 cannot move independently of the carrier member 414, e.g., such that the plug member 412 may be rotated only by rotating the carrier member 414.

Preferably, the handle 442 includes an actuator 443 that may be activated to release the connector(s) securing the plug member 412 to the distal end 436 of the carrier member

- 20 -

414. For example, the actuator 443 may include a button coupled to a control rod or wire (not shown) that extends through the carrier member 414 to the distal end 436. Upon depression of the button, the control rod may be moved, thereby disengaging the connector on the carrier member 414 from the plug member 412 or a mating connector (not shown) on the plug member 412. In another alternative, the distal end 436 of the carrier member 414 and the plug member 412 may include mating threads (not shown) such that the carrier member 414 may be rotated with respect to the plug member 412 to release the plug member 412. In this embodiment, the mating threads should wind helically in the same direction as the thread pattern 418 on the plug member 412 to ensure that the plug member 412 is not released prematurely from the carrier member 414.

The guide member 416 is an elongate member, e.g., formed from flexible or semi-rigid material, having a proximal end 444 and a substantially atraumatic and/or flexible distal tip 446, e.g., having a size for insertion into a passage through tissue into a blood vessel or other body lumen (not shown). An elongate groove 448 defined by opposing edges 449 is provided in an external surface 450 that extends from the proximal end 444 to the distal tip 446. Alternatively, the groove 448 may terminate before to the distal tip 446, e.g., a predetermined distance proximal to the distal tip 446 (not shown).

The guide member 416 has a size and shape for slidable insertion through the lumen 440 of the carrier member 414 and through the lumen 424 of the plug member 412. During use, the guide member 416 may be inserted through the carrier member 414 such that the distal tip 46 of the guide member 416 extends beyond the distal end 422 of the plug member 412, as shown in FIG. 7B.

Preferably, as shown in FIG. 9A, the lumen 424 in the plug member 412 has a cross-section, e.g., diameter, similar to that of the guide member 416 such that edges 449 of the groove 448 slidably engage an inner wall 425 of the plug member 412. Thus, the plug member 412 and guide member 416 may together define a lumen 451, which is generally referred to as a bleed back lumen (although it may receive other fluids in addition to or instead of blood). Similarly, the lumen 440 in the carrier member 414 may also have a cross-section similar to and aligned with the lumen 424 in the plug member 412, thereby further defining the bleed back lumen 451.

In alternative embodiments, shown in FIGS. 9B-9F, the guide member 416<sub>a</sub>-416<sub>e</sub> may have one of a variety of cross-sections, thereby providing one or more bleed back

lumens 451<sub>a</sub>-451<sub>e</sub> defined by edges 449<sub>a</sub>-449<sub>e</sub> of one or more respective grooves 448<sub>a</sub>-448<sub>e</sub> in the guide member 416<sub>a</sub>-416<sub>e</sub> and an inner wall 425 of the plug member 412. In addition, the grooves 448 may have one of a variety of shapes, such as the exemplary concave, notched, or flat cross-sections shown in FIGS. 9B-9F. Thus, any number of bleed back lumens, having any desired shape may be provided in the apparatus 410.

Turning to FIGS. 10A-10D, during use, the apparatus 410 may be used to seal and/or close a passage through tissue 96, such as a puncture 92 communicating with a blood vessel 90 or other body lumen. The puncture 92 may be used to provide percutaneous access through a wall 98 of the vessel 90 into the vessel lumen 94. For example, the puncture 92 may facilitate performing an endovascular procedure within a patient's vasculature, such as angioplasty, stenting, atherectomy, and the like, or may otherwise provide access via the vessel 90 to a region within the patient's body.

Upon completion of the procedure, any instruments, such as an introducer sheath (not shown), may be removed from the vessel 90 and puncture 92. If a guidewire 102 is used during the procedure, the guidewire 102 may be removed before delivering the plug member 412. Alternatively, however, the guidewire 102 may be used to guide the plug member 412 into position, as described below. In a further alternative, an introducer sheath (not shown), such as that used to previously introduce instruments into the vessel 90 may be left in place, and the guidewire 102 may be removed.

Initially, the guide member 416 is introduced into the puncture 92, for example, by inserting the distal tip 446 of the guide member 416 into the puncture 92 and advancing the distal tip 446 until it enters the vessel 90, as shown in FIG. 10A. If the guidewire 102 is in place, generally as shown, the guidewire 102 may be backloaded into a guidewire lumen 456 in the guide member 416 in a conventional manner before inserting the distal tip 446 into the puncture 92. Alternatively, if an introducer sheath is left in place, the guide member 416 may be advanced through a lumen of the introducer sheath.

As the distal tip 436 enters the vessel 90 (e.g., over the guidewire 102 or through an introducer sheath), capillary action may cause a relatively small amount of blood, represented by v<sub>1</sub>, to travel proximally along the groove 448 to the proximal end 444 of the guide member 416. Because the groove 448 does not provide a substantially enclosed lumen, however, much (and preferably most) of the blood entering the puncture 92 may be dispersed within subcutaneous tissue, e.g., adjacent to the wall 98 of the vessel 90, as

- 22 -

represented by  $v_2$ , and not travel to the proximal end 444 of the guide member 416. If a guidewire and/or an introducer sheath is used to direct the guide member 416 into the vessel 90, they may be removed once the distal tip 436 is positioned within the vessel 90.

- The plug member 412 may then be advanced over the guide member 416 into the
- 5 puncture 92, as shown in FIG. 10B. Preferably, the proximal end 446 of the guide member 416 is inserted into the lumen 424 in the plug member 412. The plug member 412 is then advanced over the guide member 416 and into the puncture 92 until the proximal end 446 of the guide member 416 passes through the lumen 440 in the carrier member 414 and exits the lumen 440 at the proximal end 436 of the carrier member 414.
- 10 Optionally, the carrier member 414 may not include a lumen and a separate lumen member (not shown) may be provided that communicates with the lumen 424 in the plug member 412.

- Preferably, the lumens 424, 440 in the plug member 412 and/or the carrier member 414 have a cross-section, e.g., diameter, similar to that of the guide member 416 such that
- 15 the groove 448 and the lumens 424, 440 define a bleed back lumen 451, as described above. Thus, as the plug member 412 is advanced over the guide member 416, the bleed back lumen 451 is also advanced distally.

- If the plug member 412 includes a thread pattern 418 (as shown in FIG. 8B), the carrier member 414 may be rotated in a first direction to thread the plug member 412 into
- 20 the puncture 92. Because the plug member 412 is coupled to the carrier member 414, as the carrier member 414 is rotated, the plug member 412 is rotated and threaded into the puncture 92 towards the vessel 90. Consequently, the outer surface 430 and thread pattern 418 of the plug member 412 may engage tissue 96 surrounding the puncture 92, thereby substantially sealing the puncture 92 from fluids, such as blood, within the vessel 90.

- One advantage of providing an external thread on the plug member 412 is that the thread pattern 418 may facilitate advancement of the plug member 412 through layers of tissue (not shown) towards the vessel 90. For example, the tissue 96 may include one or more intermediate layers of fascia or other tissue structures disposed between layers of fat (also not shown). The fascia layer may be relatively thin, yet resilient and tough, and
- 30 therefore it may be difficult to advance a device axially through the layer without deflecting the layer towards the vessel 90.



- 23 -

When the plug member 412 is advanced through the wall 98 of the vessel 90, as shown in FIG. 10C, the bleed back lumen 451 may become exposed to fluid, e.g., blood, within the vessel 90. Because of internal blood pressure, the fluid may enter the bleed back lumen 451 (not shown, see FIG. 8A), pass through the lumens 424, 440 in the plug member 412 and the carrier member 414, and exit the proximal port 454 of the carrier member 414, as represented by  $v_3$ , thereby providing a visual indication that the vessel 90 has been attained. If a relatively low rate of fluid flow was previously observed, a substantially higher rate of fluid flow may be observed, because fluid entering the puncture 92 may no longer be dispersed within the subcutaneous tissue, but pass instead through the bleed back lumen 451. This visual indication from the proximal port 454 may provide feedback that the distal end 422 of the plug member 412 has reached the vessel 90, as will be appreciated by those skilled in the art.

If desired, the carrier member 414 may then be withdrawn partially to move the plug member 412 to a predetermined deployment depth, e.g., offset proximally from the wall 98 of the vessel 90. For example, bleed back may occur when the plug member 412 is within or in close proximity to the vessel 90, as shown in FIG. 10C. If the plug member 412 includes an external thread, rotation of the apparatus 410 may be reversed, i.e., in a second direction opposite the first direction, to withdraw the plug member 412 a predetermined distance relative to the vessel 90. If no external thread is provided, the carrier member 414 may simply be pulled proximally. Otherwise, the plug member 412 may be left in place, e.g., in contact with the wall 98 of the vessel 90.

Once the desired deployment location is attained, the plug member 412 may be released from the carrier member 414, e.g., by depressing actuator 43. The guide member 416 may be withdrawn from the plug member 412 and carrier member 414 either before or after releasing the plug member 412. The sealing member 432 preferably substantially seals the lumen 424 within the plug member 412 thereafter to prevent fluid within the vessel 90 from passing therethrough to leak from the puncture 92.

For example, as explained above, the sealing member 432 may include a material that expands when exposed to fluid. As the guide member 416 is withdrawn, fluid, e.g., blood, may flow proximally through the lumen 424 in the plug member 412, e.g., until it encounters the sealing member 432. Although a relatively small amount of fluid may pass beyond the sealing member 432, the sealing member 432 may expand relatively quickly

due to the fluid contact until it substantially seals the lumen 424. Alternatively, the sealing member 432 may be a valve that may automatically open to accommodate the guide member 416, but may automatically close upon withdrawal of the guide member 416. In a further alternative, the sealing member 432 may be manually actuated by the user.

- 5           Finally, as shown in FIG. 10D, the carrier member 414 and the guidewire 102 (if still in place) may be withdrawn, leaving the plug member 412 in place to substantially seal the puncture 92. If the plug member 412 is bioabsorbable, it may remain within the puncture 92 as the tissue heals, thereby allowing the wall 98 of the vessel 90 and tissue 96 surrounding the passage 92 to at least partially heal before the plug member 412 is
- 10          absorbed. Alternatively, the plug member 412 may be retrieved once the tissue between the plug member 412 and the vessel 90 has substantially healed, as described in the applications incorporated above.

- Turning to FIGS. 11A-11B, yet another embodiment of an apparatus 510 is shown that includes a plug member 512 and a handle device 514. The plug member 512 includes
- 15          a body, preferably formed from bioabsorbable material, including a proximal end 520 and a distal end 522. An outer surface 530 of the plug member 512 may be substantially smooth or may include a helical thread pattern (not shown) extending along the outer surface 530 at least partially between the proximal and distal ends 520, 522, similar to the embodiment described above.

- 20          In addition, the plug member 512 includes a lumen 524 that extends between a proximal opening 526 and a distal opening 528 generally parallel to a longitudinal axis 538. An inner lip 525 is provided within the lumen 524, e.g., adjacent the distal end 522 of the plug member 512, which may be a continuous annular ridge or a plurality of tabs.

- A sealing member 532 is disposed within the lumen 524 in an open position
- 25          (shown in FIG. 11A) adjacent the inner lip 525. The sealing member 532 is a generally annular-shaped member, preferably a coil of material including one or more overlapping layers, which may be formed from a biocompatible, and preferably a bioabsorbable material, similar to the plug member 512. Alternatively, the sealing member 532 may be an enclosed ring that may be formed from semi-rigid or flexible material. In the open
- 30          position, the lumen 524 is substantially open, i.e., the sealing member 532 does not generally obstruct the lumen 524. The sealing member 532 is compressible distally against the lip 525 to become compressed or wedged therein (as shown in FIG. 11B),

- 25 -

thereby defining a closed position for substantially sealing the lumen 524 from fluid flow therethrough.

The handle device 514 includes an outer carrier tube 534, and an inner delivery tube 536, the inner tube 536 being coaxially and/or slidably disposed within the outer tube 534. The handle device 514 may include a handle and/or actuator (not shown) on a proximal end of the handle device 514 for manipulating the handle device 514 and/or for controlling movement of the inner tube 536 relative to the outer tube 534. A distal end 540 of the outer tube 534 may be received in an annular recess 527 to couple the plug member 512 to the handle device 514. The distal end 540 may frictionally engage a wall of the recess 527, e.g., providing a desired resistance to removing the distal end 540 from the recess 527. In addition or alternatively, the distal end 540 and/or the plug member 512 may include one or more detents or connectors (not shown), similar to the embodiment described above.

A distal end 542 of the inner tube 536 preferably has a size for being slidably received within the lumen 524 and substantially abutting the sealing member 532. The inner tube 536 preferably includes a lumen 544 that communicates with the lumen 524. Thus, the lumens 544, 524 may provide a lumen for receiving a guide member (not shown), such as that shown and described in connection with FIG. 7A.

Use of the apparatus 510 proceeds similar to the previous embodiment, except that the sealing member 532 is manually activated, rather than being activated automatically upon fluid contact. The apparatus 510 is assembled by inserting the distal end 540 of the outer tube 534 into the recess 527 and the distal end 542 of the inner tube 536 into the lumen 524, as shown in FIG. 11A. A guide member (not shown) may be directed into a passage communicating with a vessel, e.g., through an introducer sheath, which is then removed once a distal end of the guide member is positioned within the vessel, similar to the previous embodiment.

The plug member 512 is inserted into the passage over the guide member until the distal end 522 of the plug member 512 enters the vessel. As the plug member 512 enters the vessel, a bleed back lumen defined by a groove (not shown) in the guide member and the wall of the lumen 524 becomes exposed to the interior of the vessel, causing fluid to flow into the bleed back lumen to a proximal outlet port or other bleed back indicator (not shown) on the handle device 514.

The inner tube 536 may then be advanced distally relative to the outer tube 534, thereby engaging the sealing member 532 and forcing it distally against the inner lip 525. Because of its inherent flexibility and/or because of its coil shape, the sealing member 532 may compress and/or become crushed, wedging the sealing member 532 within the lumen 524 and sealing the lumen 524 from fluid flow therethrough, as shown in FIG. 11B. In addition, a distal portion of the sealing member 532 may be attached to an inner wall of the plug member 512 defining the lumen 524, e.g., by an adhesive, sonic welding, and the like. Alternatively, if the sealing member 532 is attached to the inner wall, the lip may be eliminated (not shown).

The plug member 512 may be released from the handle device 514, e.g., by withdrawing the outer tube 536 and/or by releasing connectors securing the plug member 512 to the distal end 540 of the outer tube 534. The handle device 514 may then be withdrawn from the passage, leaving the plug member 512 in place, similar to the embodiment described above.

Turning to FIG. 12, another embodiment of an apparatus 610 is shown that includes a plug member 612 and a handle device 614. The plug member 612 includes a tapered body, preferably formed from bioabsorbable material, including a proximal end 620 and a distal end 622. Preferably, the plug member 612 is continuously tapered from the proximal end 620 towards the distal end 622, although alternatively, only a distal portion of the plug member 612 may be tapered (not shown). The plug member 612 may have a substantially constant taper or the taper rate may vary along the length of the plug member 612 (not shown). The distal end 622 may be substantially rounded or blunt, may include a concave distal tip as shown, and/or may be pointed (not shown).

In addition, the plug member 612 includes a lumen 624, and may include a sealing member 632 disposed within the lumen 624, similar to the embodiments described above. The lumen 624 communicates with a distal port 628 that is located on or adjacent the distal end 622 of the plug member 612.

A helical thread pattern 618 extends along an outer surface 630 of the plug member 612 at least partially between the proximal and distal ends 620, 622.

Alternatively, the outer surface 630 may be substantially smooth or may include gripping elements for allowing distal advancement but preventing proximal withdrawal of the plug

member 612 from within a passage through tissue, similar to the embodiments described above.

The handle device 614 is an elongate member having a proximal end 634, a distal end 636, and a lumen 640 extending therebetween. Preferably, the plug member 612 and the handle device 614 include cooperating elements (not shown) for coupling the plug member 612 to the handle device 614, i.e., to prevent rotation of the plug member 612 relative to the handle device 614. For example, cooperating connectors (not shown) may be provided for releasably securing the plug member 612 to the distal end 636 of the handle device 614, similar to the embodiment described above. If the plug member 612 has an internal sealing member (not shown), the handle device 614 may include an internal member, e.g., inner tube (also not shown), for wedging or otherwise activating the sealing member.

Turning to FIGS. 13A-13B, during use, the apparatus 610 may be used to seal and/or close a passage through tissue 96, such as a puncture 92 used to access a blood vessel 90 during an endovascular procedure, similar to the embodiment described above. Upon completion of the procedure, any instruments, such as an introducer sheath, a guidewire, and the like (not shown), may be removed from the vessel 90 and puncture 92.

As shown in FIG. 13A, the distal end 622 of the plug member 612 may be inserted into the puncture 92, and the handle device 614 rotated in a first direction to advance the plug member 612 into the puncture 92. Because the plug member 612 is coupled to the handle device 614, rotation of the handle device 614 preferably threads the plug member 612 into the puncture 92 towards the vessel 90. Consequently, the outer surface 630 and/or the thread pattern 618 of the plug member 612 may engage tissue 96 surrounding the puncture 92, thereby substantially sealing the puncture 92 from fluids, such as blood, within the vessel 90. In addition, the thread pattern 618 may facilitate advancing the plug member 612 through any intervening layers of tissue, e.g., one or more layers of fascia (not shown), similar to the embodiments described above.

As shown in FIG. 13B, when the distal end 622 of the plug member 612 is advanced through the wall 98 of the vessel 90, the distal port 628 becomes exposed to fluid, e.g., blood, within the vessel 90. Because of internal blood pressure, the fluid may enter the distal port 628 and pass through the lumens 624, 640, thereby providing a visual indication that the vessel 90 has been attained, similar to the embodiment described above.

- 28 -

The plug member 612 may then be released from the handle device 614, e.g., by activating an actuator (not shown, see FIG. 12) on the proximal end of the handle device 614, and the handle device 614 withdrawn from the passage 92. Preferably, the distal end 622 of the plug member 612 does not extend substantially into the vessel 90, thereby minimizing obstruction of the lumen 94. The tapered profile of the plug member 612 may substantially anchor the plug member 612 within the passage 92 and/or enhance sealing the passage 92 from fluid flow.

Alternatively, after bleed back indicates that the distal end 622 is located within the vessel 90, rotation of the handle device 614 may be reversed, i.e., in a second direction opposite the first direction, to withdraw the plug member 612 a predetermined distance relative to the vessel 90. Once the desired deployment location is attained, the plug member 612 may be released from the handle device 614. The handle device 614 may be withdrawn, leaving the plug member 612 in place to substantially seal the passage 92.

As fluid flows through the lumen 624, the sealing member 632 may expand to substantially seal the lumen 624 to prevent further fluid within the vessel 90 from passing therethrough to leak from the puncture 92. Alternatively, the lumen 624 may be sufficiently small that the sealing member 632 may be eliminated, and may seal as hemostasis occurs. In a further alternative, the sealing member 632 may be manually wedged or otherwise closed to seal the lumen 624.

If the plug member 612 is bioabsorbable, it may remain within the puncture 92 as the tissue heals, thereby allowing the wall 98 of the vessel 90 and tissue 96 surrounding the passage 92 to at least partially heal before the plug member 612 is absorbed. Alternatively, the plug member 612 may be retrieved once the tissue between the plug member 612 and the vessel 90 has substantially healed.

Apparatus in accordance with the present invention may be used for procedures other than a surgical procedure. For example, an apparatus in accordance with the present invention may be used to seal temporarily or indefinitely other passages, such as wounds, punctures, and the like that extend through tissue. The apparatus may be used in an emergency setting, e.g., to seal a bullet wound or other puncture temporarily until the patient may be subsequently treated and/or transported to a location where conventional surgery or other treatment may be performed.

- 29 -

The apparatus may be removably introduced into the passage to seal it and/or may be deployed within the passage. A bleed back lumen, such as that described above, may be used to position the apparatus. Alternatively, flow through a blood vessel or other body passage proximate the passage may be monitored to position the plug member relative to the vessel, similar to the methods described above.

Turning to FIGS. 14A, 14B, and 15, another preferred embodiment of an apparatus 710 for sealing a passage through tissue, in accordance with the present invention. Generally, the apparatus 710 includes a plug member 712, an elongate shaft or handle device 714, and an obturator 716.

The plug member 712 is a substantially rigid body, preferably having a generally cylindrical shape, including a proximal end 720, a distal end 722, and an outer surface 730. The plug member 712 includes a lumen 724 that extends between a proximal opening 726 and a distal opening or port 728.

The plug member 712 may be formed from a biocompatible material, e.g., a plastic, such as polyethylene or polyester. Preferably, the plug member 712 is formed at least partially (and more preferably entirely) from bioabsorbable material, such as collagen, polyglycolic acids (PGA's), polylactides (PLA's), and the like, that may be at least partially absorbed by the patient's body over time. Alternatively, the plug member 712 may be a semi-rigid or flexible body or may have a substantially flexible distal tip (not shown), e.g., to facilitate atraumatic insertion of the plug member 712 into the passage. In addition or alternatively, the plug member 712 may be tapered along its length, and/or the distal end 722 may be rounded to facilitate advancement of the plug member 712 into a passage through tissue.

In a preferred embodiment, the plug member 712 has a length of not more than about ten millimeters (10 mm), and more preferably between about one and ten millimeters (1-10 mm). The plug member 712 also preferably has a diameter of between about one and twenty millimeters (1-20 mm). Preferably, the length and diameter have a ratio that not more than about two-to-one.

The plug member 712 generally includes a helical thread pattern 718, including one or more helical threads, that extend at least partially between its proximal and distal ends 720, 722. Preferably, the thread pattern 718 extends completely to the distal end 722 of the plug member 712, and may be tapered at the distal end 722 to facilitate introduction

- 30 -

into a passage through tissue (not shown). The helical thread 718 is preferably substantially rigid and may have a substantially square cross-section to facilitate sealing of a passage into which the plug member 712 is threaded. In a preferred embodiment, the helical thread 718 is integrally formed on the outer surface 730 of the plug member 712.

5 For example, the plug member 712 and thread 718 may be formed by injection molding. Alternatively, the threads may be cut or otherwise formed in the outer surface 730 of the plug member 712.

As best seen in FIG. 15 (in which the handle device 714 has been eliminated for convenience), a sealing member 732 is provided within the lumen 724 for substantially

10 sealing the lumen 724 from fluid flow therethrough. In a preferred embodiment, the sealing member 732 has an annular shape, and is mounted within an annular recess 733 in the lumen 724. The sealing member 732 is preferably formed from a material that expands when exposed to fluids, e.g., an expandable foam. More preferably, the sealing member 732 is also bioabsorbable, similar to the plug member 712 itself. Exemplary

15 materials that may be appropriate for use in the sealing member 732 and/or for the plug member 712 are disclosed in U.S. Patent No. 6,924,630, the disclosure of which is expressly incorporated herein by reference. Alternatively, the sealing member 732 may be a valve (not shown) that is biased to substantially seal the lumen 724 from fluid flow, but may be opened to facilitate introduction of one or more devices, e.g., the obturator 716

20 therethrough, as described further below.

In an alternative embodiment, the plug member 712 may include a cavity (not shown) in the distal end 722. A material (also not shown) may be provided in the cavity, such as extra-cellular matrix material, e.g., intestinal, stomach, or bladder submucosa, collagen, an infection-resistant material, and the like, that may promote hemostasis and/or

25 healing of the tissue. Alternatively, such material may be otherwise detachably secured to the distal end 722 of the plug member 712, either within a cavity or across the distal end 722 without a cavity. For example, the material may be secured using a biodegradable adhesive or a mechanical fastener, such as one or more clips (not shown).

Returning to FIGS. 14A and 14B, the handle device 714 has a proximal end 734

30 and a distal end 736, and defines a longitudinal axis 738 that extends between the proximal and distal ends 34, 736. A lumen 740 also extends between the proximal and distal ends 734, 736, e.g., for accommodating insertion of the obturator 716 therethrough.



- 31 -

A handle 742 may be provided on the proximal end 734 of the handle device 714 for facilitating manipulation of the apparatus 710, e.g., to facilitate rotation of the apparatus 710 into a passage, as described below.

5 Preferably, the handle device 714 is a substantially rigid tubular member, formed from a biocompatible material, e.g., plastic, such as polyethylene or polyester, or metal, such as stainless steel. The handle device 714 preferably has a cross-section that is substantially smaller than a cross-section of the plug member 712, e.g., to minimize dilation of a passage into which the apparatus 710 is inserted.

At least one of the plug member 712 and the distal end 736 of the handle device 10 714 include a connector. Preferably, the plug member 712 and the distal end 736 of the handle device 714 include cooperating connectors (not shown) for releasably securing the plug member 712 to the handle device 14, as described in application Serial No. 09/738,431, incorporated above. Preferably, the cooperating connectors substantially couple the plug member 712 to the handle device 714 such that the plug member 712 15 cannot move independently of the handle device 714, e.g., such that the plug member 712 may be rotated only by rotating the handle device 714.

For example, the plug member 712 may include a recess (not shown) in its proximal end 720 and the handle device 714 may include a mechanism, e.g., a frame and/or radially projecting fingers (not shown), for frictionally engaging the wall of the 20 recess. Alternatively, the recess may include slots for positively receiving the mechanism on the handle device 714. In a further alternative, the plug member 712 may include a hub (not shown) extending from its proximal end 720 and the handle device 714 may include a mechanism for detachable securing the hub to the handle device 714.

Preferably, the handle 742 includes an actuator (not shown) that may be activated 25 to release the connectors securing the plug member 712 to the handle device 14. For example, the actuator may include a button coupled to a control rod or wire (not shown) that extends through the handle device 714 to its distal end 36. Upon depression of the button, the control rod may be moved, thereby disengaging the connector on the handle device 714 from the mating connector on the plug member 712. In another alternative, the 30 distal end 736 of the handle device 714 and the plug member 712 may include mating threads (not shown) so that the handle device 714 may be rotated with respect to the plug member 712 to release the plug member 712. In this embodiment, the mating threads

- 32 -

should wind helically in the same direction as the thread pattern 718 on the plug member 712 to ensure that the plug member 712 is not released prematurely from the handle device 714.

The obturator 716 is an elongate member, preferably having a proximal end 744 and a substantially atraumatic and/or flexible distal tip 746. An inlet or bleed back port 748 is provided on the distal tip 746, and a bleed back lumen 750 extends from the inlet port 748 to the proximal end 744. The proximal end 744 may include an outlet port 752, which may include any conventional structure for detected or observing fluid passing from the back bleed lumen 750.

The obturator 716 has a size and shape for insertion through the lumen 740 of the handle device 714 and through the lumen 724 of the plug member 12. Once the obturator 716 is fully received through the handle device 14, the distal tip 46 of the obturator 716 may extend beyond the distal end 722 of the plug member 712, as shown in FIG. 14B. The obturator 716 and the handle device 714 may include cooperating detents (not shown) for securing the obturator 716 once it is fully received through the handle device 714 and plug member 712. The detents may substantially permanently or releasably couple the obturator 716 to the handle device 714.

In alternative embodiments, an expandable member (not shown) may be provided on or adjacent the distal tip 746 of the obturator 716, in addition to or instead of the bleed back port and lumen 748, 750. The expandable member may be expandable, e.g., when the distal tip is disposed within a body lumen, for providing tactile feedback of a location of the distal end of the plug member with respect to the body lumen. The expandable member may be a balloon, one or more expandable wings, such as those disclosed in application Serial No. 09/732,835, filed December 7, 2000, or a helical tether device. The disclosures of these applications and any other references cited therein are expressly incorporated herein by reference.

Turning to FIGS. 16A-16D, during use, the apparatus 710 may be used to seal and/or close a passage through tissue 96, such as a puncture 92 communicating with a blood vessel 90 or other body lumen. The puncture 92 may be used to provide percutaneous access to the vessel 90. For example, the puncture 92 may facilitate performing an endovascular procedure within a patient's vasculature, such as angioplasty,

stenting, atherectomy, and the like, or may otherwise provide access via the vessel 90 to a region within the patient's body.

Upon completion of the procedure, any instruments, such as an introducer sheath (not shown), may be removed from the vessel 90 and puncture 92. If a guidewire 102 is used during the procedure, the guidewire 102 may be removed before delivering the plug member 712, or preferably, the guidewire 102 may be used to guide the plug member 712 into position, as described below.

Initially, the apparatus 710 is assembled as shown in FIG. 14B, i.e., the plug member 712 is connected to the handle device 714, and the obturator 716 is inserted through the handle device 714 and plug member 712. The apparatus 710 may then be introduced into the puncture 92, for example, initially by inserting the distal tip 746 of the obturator 716 into the puncture 92. If the guidewire 102 is in place, generally as shown, the guidewire 102 may be backloaded into a guidewire lumen (not shown) in the obturator 716 in a conventional manner before inserting the distal tip 746 into the puncture 92.

As the obturator 716 is advanced into the puncture 92 (e.g., over the guidewire 102), the plug member 712 is inserted into the puncture 92, as shown in FIG. 16A. Because of the thread pattern 718, the handle device 714 is then rotated in a first direction to thread the plug member 712 into the puncture 92. Consequently, the outer surface 730 and thread pattern 718 engage tissue 96 surrounding the puncture 92, thereby substantially sealing the puncture 92 from fluids, such as blood, within the vessel 90. The apparatus 710 may then be rotated in a first direction about its longitudinal axis 738 to thread the plug member 712 substantially atraumatically deeper into the puncture 92.

Turning to FIG. 16B, as the plug member 712 is advanced, the thread pattern 718 may facilitate advancement of the plug member 712 through layers of tissue towards the vessel 90. For example, the tissue 96 may include one or more intermediate layers of fascia 99 or other tissue structures disposed between layers of fat. The fascia layer 99 may be relatively thin, yet resilient and tough, and therefore it may be difficult to advance a device axially through the layer 99 without deflecting the layer 99 towards the vessel 90. Because of the thread pattern 718, a plug member 712 in accordance with the present invention may be threaded or screwed through the fascia layer 99 towards the vessel 90. This may substantially reduce the risk of the fascia layer 99 being deflected towards the vessel 90 as the plug member 712 is advanced towards the vessel 90, thereby minimize

deflection of the plug member 712 away from the vessel 90 once released within puncture 92 that may otherwise occur if the fascia layer 99 is compressed towards the vessel 90.

When the plug member 712 is advanced into the puncture 92, the distal tip 746 of the obturator 716 eventually passes through the wall 98 of the vessel 90, whereupon the bleed back port 748 becomes exposed to fluid, i.e., blood, within the vessel 90. Because of internal blood pressure, the fluid enters the bleed back port 748, passes through the bleed back lumen 750 (not shown in FIGS. 16A-16D), and exits the outlet port 752 (as represented by drops 754), thereby providing a visual indication that the vessel 90 has been attained. Because of the relative lengths of the plug member 712, the handle device 714, and the obturator 716, this visual indication provides feedback on the location of the distal end 722 of the plug member 712 relative to the vessel 90, as will be appreciated by those skilled in the art. The relative lengths may be predetermined such that the plug member 712 is at a preferred deployment depth when the bleed back indication is observed. For example, the deployment depth may place the plug member 712 in close proximity to the vessel 90, e.g., without exposing the distal end 722 within the vessel 90.

Preferably, the relative lengths may be such that the apparatus 710 needs to be counter-rotated to attain the preferred deployment depth. For example, bleed back may occur when the plug member 712 is within or in close proximity to the vessel 90, as shown in FIG. 16B. Rotation of the apparatus 710 may then be reversed, i.e., in a second direction opposite the first direction, to withdraw the plug member 712 a predetermined distance relative to the vessel 90, as shown in FIG. 3C. Because of the known pitch of the thread pattern 718, the distance that the plug member 712 is moved relative to the vessel 90 may be related directly to the number of rotations and/or partial rotations that the apparatus 710 is counter-rotated.

Once the desired deployment location is attained, the plug member 712 may be released from the handle device 714. The obturator 716 may be withdrawn from the plug member 712 and handle device 714 either before or after releasing the plug member 12. The sealing member 732 (not shown, see FIG. 15) preferably substantially seals the lumen (not shown, see FIG. 15) within the plug member 712 to prevent fluid within the vessel 90 from passing therethrough to leak from the puncture.

Preferably, as explained above, the sealing member 732 is a material that expands when exposed to fluid. For example, as the obturator 716 is withdrawn, fluid, e.g., blood,

- 35 -

may flow proximally through the lumen 724 in the plug member 712, e.g., until it encounters the sealing member 732. Although a relatively small amount of fluid may pass beyond the sealing member 732, the sealing member 732 may expand substantially due to the fluid contact until it substantially seals the lumen. Alternatively, the sealing member 732 may be a valve that may open to accommodate the obturator 716, but may automatically close upon withdrawal of the obturator 716.

Finally, as shown in FIG. 16D, the handle device 714 and the guidewire 102 (if still in place) may be withdrawn, leaving the plug member 712 in place to substantially seal the puncture 92. If the plug member 712 is bioabsorbable, it may remain within the puncture 92 as the tissue heals, thereby allowing the wall 98 of the vessel 90 and tissue 96 surrounding the passage 92 to at least partially heal before the plug member 712 is absorbed. Alternatively, the plug member 712 may be retrieved once the tissue between the plug member 712 and the vessel 90 has substantially healed, as described in the application incorporated above.

Turning to FIGS. 17A and 17B, another embodiment of an apparatus 810 is shown that includes a plug member 812 and a handle device 814. The plug member 812 includes a body, preferably formed from bioabsorbable material, including a proximal end 820 and a distal end 822. A helical thread pattern 818 extends along an outer surface 830 of the plug member 812 at least partially between the proximal and distal ends, similar to the embodiment described above. In addition, the plug member 812 includes a lumen 824 and a sealing member 832 disposed within the lumen 824, similar to the embodiment described above.

The handle device 814 is an elongate member having an enlarged portion 834 and a reduced portion 836 defining a shoulder 838 therebetween. The enlarged portion 834 may include a handle 842 on the proximal end 840. The reduced portion 836 has a size for insertion through the lumen 824 of the plug member 812 and terminates in a distal tip 846 that may be substantially atraumatic and/or flexible, similar to the obturator distal tip described above. A bleed back port 848 is provided in the distal tip 846 that communicates with a bleed back lumen 850 that extends to an outlet port 852 in the proximal end 840.

As shown in FIG. 17B, the reduced portion 836 may be inserted into the lumen 824 until the distal tip 846 extends beyond the distal end 822 of the plug member 812 and/or

the shoulder 838 abuts the proximal end 820 of the plug member 812. Alternatively, the shaft of the handle device 814 may have a substantially uniform cross-section, similar to the reduced portion 834, and a raised portion (not shown) may be provided on the shaft, e.g., an annular ridge against which the plug member 812 may abut. Thus, the shoulder  
5 838 or other raised portion may limit proximal movement of the plug member 812 relative to the handle device 814.

Preferably, the plug member 812 and the handle device 814 include cooperating elements (not shown) for coupling the plug member 812 to the handle device 814, i.e., to prevent rotation of the plug member 812 relative to the handle device 814. For example,  
10 all or a portion of the reduced portion 836 of the handle device 814 may have a noncircular cross-section, and all or a mating portion of the lumen 824 may have a complementary noncircular cross-section. Alternatively, cooperating longitudinal slots and tabs and the like may be provided on the reduced portion 836 and within the lumen 824 of the plug member 814. Thus, when the reduced portion 836 is fully inserted through  
15 the lumen 824, rotation of the plug member 812 may be coupled to rotation of the handle device 814. In a further alternative, the plug member 812 and the handle device 814 may include connectors that may releasably couple the plug member 812 to the handle device 814, similar to the embodiment described above.

The apparatus 810 may be used to seal and/or close a passage through tissue, such  
20 as a puncture communicating with a blood vessel or other body lumen (not shown), similar to the embodiment described above. Upon completion of a procedure accessed via the puncture, any instruments may be removed from the vessel and puncture, although a guidewire (not shown) may remain, similar to the embodiment described above. The apparatus 810 may be assembled as shown in FIG. 17B, i.e., with reduced portion 834 of  
25 the handle device 814 fully inserted into the plug member 812. The distal tip 846 may be inserted into the puncture, e.g., over a guidewire (not shown) if still in place within the puncture, until the plug member 812 is inserted into the puncture 92.

The apparatus 810 may then be rotated to thread the plug member 812 into the puncture such that the outer surface 830 and thread pattern 818 engage tissue surrounding  
30 the puncture to substantially seal the puncture. When the distal tip 846 enters the vessel, the bleed back port 848 becomes exposed to blood within the vessel. Because of internal blood pressure, fluid within the vessel enters the port 848, passes through the bleed back

- 37 -

lumen 850, and exits the outlet port 852, thereby providing a visual indication that the vessel has been attained.

If desired, rotation of the apparatus 810 may then be reversed to withdraw the plug member 812 a predetermined distance relative to the vessel. The plug member 812 may then be released from the handle device 814. The handle device 814 may then be withdrawn from the plug member 812 (and the guidewire, if still present). Preferably, the reduced portion 834 of the handle device 814 may simply be withdrawn from within the lumen 824, without requiring disengagement of connectors, which may simplify construction of the handle device 814 compared to the embodiment described above. As the reduced portion 834 is withdrawn from the lumen 824, the sealing member 832 becomes exposed to fluid passing through the lumen 824. Preferably, as explained above, the sealing member 832 expands when exposed to the fluid to substantially seal the lumen 824 from subsequent fluid flow. Alternatively, the sealing member 832 may be a valve or an element that may controllably open or closed (not shown).

Turning to FIG. 18, yet another embodiment of an apparatus 910 is shown that includes a plug member 912 and a handle device 914. The plug member 912 includes a body, preferably formed from bioabsorbable material, including a proximal end 920, a distal end 922, and a helical thread pattern 918 that extends along an outer surface 930 at least partially between the proximal and distal ends 920, 922, similar to the embodiment described above. In addition, the plug member 912 includes a lumen 924 including an inlet or bleed back port 248 and a sealing member (not shown) disposed within the lumen 924. Alternatively, the lumen 924 may have a sufficiently small cross-section that a sealing member may not be necessary.

The handle device 914 has a proximal end 934 and a distal end 936, and defines a longitudinal axis 238 that extends between the proximal and distal ends 934, 936. A lumen 240 also extends between the proximal and distal ends 934, 936. A handle 942 may be provided on the proximal end 934 of the handle device 914 for facilitating manipulation of the apparatus 910, e.g., to facilitate rotation of the apparatus 910 into a passage, similar to the embodiments described above. An outlet port 952 is provided on the proximal end 934, e.g., in the handle 942, that communicates with the lumen 940. Preferably, the handle device 914 is a substantially rigid elongate shaft formed from biocompatible

material. The handle device 914 preferably has a cross-section that is substantially smaller than a cross-section of the plug member 912, similar to the embodiments described above.

The plug member 912 and the distal end 936 of the handle device 914 generally include cooperating connectors (not shown) for releasably securing the plug member 912 to the handle device 914, similar to the first embodiment described above. Preferably, the cooperating connectors substantially couple the plug member 912 to the handle device 914 such that the plug member 912 cannot move independently of the handle device 914, e.g., such that the plug member 912 may be rotated only by rotating the handle device 914.

Preferably, the handle 914 includes an actuator (not shown) that may be activated to release the connectors securing the plug member 912 to the handle device 914. For example, the actuator may include a button coupled to a control rod or wire (not shown) that extends through the handle device 914 to its distal end 936. Upon depression of the button, the control rod may be moved, thereby disengaging the connector on the handle device 914 from the mating connector on the plug member 912.

Before use, the plug member 912 may be coupled to the distal end 936 of the handle device 814. Once the plug member 912 is attached to the distal end 936, the lumen 924 in the plug member 912 communicates with the lumen 940 in the handle device 914.

The apparatus 910 may be used to seal and/or close a passage through tissue, similar to the embodiments described above. After performing a procedure accessed via the puncture, the distal end 936 of the plug member 912 may be inserted into the puncture. The apparatus 910 may then be rotated to thread the plug member 912 deeper into the puncture. When the distal end 936 of the plug member 912 enters the vessel, the bleed back port 948 becomes exposed to blood within the vessel, causing fluid within the vessel to enter the port 948, pass through the lumens 924, 240, and exit the outlet port 952, thereby providing a visual indication that the vessel has been attained.

If desired, rotation of the apparatus 910 may then be reversed to withdraw the plug member 912 a predetermined distance relative to the vessel. The plug member 912 may then be released from the handle device 914. The handle device 914 may then be withdrawn, leaving the plug member 912 in place to substantially seal the puncture.

If the plug member 912 includes a sealing member, the sealing member is exposed to fluid passing through the lumen 924, causing the sealing member to expand when exposed to fluid contact to substantially seal the lumen 924 from subsequent fluid flow.



- 39 -

Alternatively, if no sealing member is provided, the lumen may be sufficiently small such that hemostasis may still occur. The lumen 924 may begin to seal on its own or, if necessary, external pressure may be applied to the puncture to promote hemostasis.

Turning to FIGS. 19A-19D, yet another embodiment of an apparatus 1010 is shown that includes a plug member 1012 and a handle device 1014. The plug member 1012 includes a body, preferably formed from bioabsorbable material, including a proximal end 1020 and a distal end 1022. A helical thread pattern 1018 extends along an outer surface 1030 of the plug member 1012 at least partially between the proximal and distal ends 1020, 1022, similar to the embodiments described above.

In addition, the plug member 1012 includes a lumen 1024 that extends between a proximal opening 1026 and a distal opening 1028 generally parallel to a longitudinal axis 1038. The lumen 1024 includes a tapered portion 1025 that tapers towards the distal end 1022. The lumen may include a proximal portion 1024a and a distal portion 1024b on either side of the tapered portion 1025 that may be substantially uniform in cross-section. Thus, the distal opening 1028 may be substantially smaller than the proximal opening 1026, e.g., corresponding to the respective portions of the tapered portion 1025. In addition, the plug member 1012 may include an annular recess 1027 disposed concentrically around the proximal opening 1026.

A sealing member 1032 is disposed in an open position adjacent the wide end of the tapered portion 1025 of the lumen 1024. The sealing member 1032 is a generally annular-shaped member, preferably a coil of material including one or more overlapping layers, which may be formed from a biocompatible, and preferably a bioabsorbable material, similar to the plug member 1012 itself. Alternatively, the sealing member 1032 may be an enclosed ring that may be formed from semi-rigid or flexible material. In its open position, the proximal portion 1024a of the lumen 1024 is substantially open, i.e., the sealing member 1032 does not generally obstruct the lumen 1024. The sealing member 1032 is movable distally into the tapered portion 1025 to become compressed or wedged therein, thereby defining a closed position for substantially sealing the lumen 1024 from fluid flow therethrough.

The handle device 1014 includes an outer carrier tube 1034, and an inner delivery tube 1036, the inner tube 1036 being coaxially and/or slidably disposed within the outer tube 1034. The handle device 1014 may include a handle and/or actuator (not shown) on a

- 40 -

proximal end of the handle device 1014 for manipulating the handle device 1014 and/or for controlling movement of the inner tube 1036 relative to the outer tube 1034. A distal end 1040 of the outer tube 1034 may be received in the annular recess 1027 to couple the plug member 1012 to the handle device 1014. The distal end 1040 may frictionally  
5 engage a wall of the recess 1027, e.g., providing a desired resistance to removing the distal end 1040 from the recess 1027. In addition or alternatively, the distal end 1040 and/or the plug member 1012 may include one or more connectors (not shown), similar to the embodiments described above.

A distal end 1042 of the inner tube 1036 preferably has a size for being slidably  
10 received into the proximal portion 1024a of the lumen 1024. Preferably, when the distal end 1040 of the outer tube 1034 is disposed within the recess 1027, the distal end 1042 of the inner tube 1036 extends into the proximal portion 1024a of the lumen 1024 in close proximity, e.g., contacting, the sealing member 1032. The inner tube 1036 preferably includes a lumen 1044 that communicates with the lumen 1024, more preferably the distal  
15 portion 1024b of the lumen 1024. Thus, the lumens 1044, 1024 may provide a bleed back lumen, similar to the embodiments described above.

During use, the apparatus 1010 is assembled by inserting the distal end 1040 of the outer tube 1034 into the recess 1027 and the distal end 1042 of the inner tube 1036 in the proximal portion 1024a of the lumen 1024, as shown in FIGS. 19A and 19B. The plug  
20 member 1012 is inserted into a passage communicating with a blood vessel or other body lumen (not shown), and threaded through the tissue towards the vessel, e.g., by rotating the apparatus 1010 in a first direction. When the distal end 1022 of the plug member 1012 enters the vessel, fluid may flow into the distal opening 1028, through the lumens 1024, 1044 to a proximal outlet port or other bleed back indicator (not shown) on the handle  
25 device 1014. If desired, the apparatus 1010 may be counter-rotated in a second direction until the plug member 1012 is disposed at a desired location within the passage.

The inner tube 1036 may then be advanced distally relative to the outer tube 1034, thereby engaging the sealing member 1032 and forcing it distally into the tapered portion 1025 of the lumen 1024. Because of its inherent flexibility and/or because of its coil  
30 shape, the sealing member 1025 may compress and/or otherwise become wedged into the tapered portion 1025, thereby substantially sealing the lumen 1024 from fluid flow therethrough, as shown in FIGS. 19C and 19D. The plug member 1012 may then be

released from the handle device 1014, e.g., by withdrawing the outer tube 1036 (without rotating it to unthread the plug member 1012) and/or by releasing connectors securing the plug member 1012 to the distal end 1040 of the outer tube 1034. The handle device 1014 may then be withdrawn from the passage, leaving the plug member 1012 in place, similar to the embodiments described above.

Turning to FIGS. 20A-20F, an apparatus 1110 is shown that includes a plug member 1112 and an elongate shaft or handle device 1114. The plug member 1112 may be formed from biocompatible and/or bioabsorbable material, similar to the embodiments described above. The plug member 1112 includes a proximal end 1120, a distal end 1122, and an outer surface 1130, and a lumen 1124 that extends between the proximal and distal ends 1120, 1122. The plug member 1112 generally includes a helical thread pattern 1118, including one or more helical threads, that extend at least partially between its proximal and distal ends 1120, 1122. A sealing member 1132 may be provided within the lumen 1124, such as those described above.

The handle device 1114 has a proximal end 1134 and a distal end 1136, and defines a longitudinal axis 1138 that extends between the proximal and distal ends 1134, 1136. In one embodiment, the handle device 1114 is tubular, and includes a lumen 1140 extending between the proximal and distal ends 1134, 1136, the lumen 1140 communicating with the lumen 1124 when the plug member 1112 is attached to the distal end 1134 of the handle device 1114. A handle 1142 may be provided on the proximal end 1134 of the handle device 1114 for facilitating manipulation of the apparatus 1110, e.g., to facilitate rotation of the apparatus 1110 into a passage.

The handle device 1114 may have a cross-section that is substantially smaller than a cross-section of the plug member 1112, e.g., to minimize dilation of a passage into which the apparatus 1110 is inserted. The plug member 1112 and/or the distal end 1136 of the handle device 1114 may include cooperating connectors (not shown) for releasably securing the plug member 1112 to the handle device 1114, as described above. Preferably, the handle 1142 includes an actuator (also not shown) that may be activated to release the connectors securing the plug member 1112 to the handle device 1114. Alternatively, the handle device 1114 may have a cross-section defining a portion of a circle, e.g., a "C" shape, or may include one or more elongate shafts (not shown) that releasably connect to the plug member 1112.

- 42 -

In addition, the plug member 1112 and the handle device 1114 include a bleed back device for providing a visual indication when the distal end 1122 of the plug member 1112 is disposed within a blood vessel 90 or other body lumen. For example, as shown, the handle device 1114 may include a bleed back lumen 1152 that extends between the proximal and distal ends 1134, 1136. An outlet port 1145, a transparent tube (not shown) or other device may be provided on the proximal end 1134 of the handle device 1114 that communicates with the bleed back lumen 1152. The plug member 1112 may include a bleed back port 1154 that extends from the distal end 1122 to the bleed back lumen 1152. For example, the bleed back port 1154 may be a separate lumen (not shown) extending between the proximal and distal ends 1120, 1122 of the plug member 1112.

Alternatively, the bleed back port 1154 may be a groove extending along the lumen 1124 of the plug member 1112, as shown in FIGS. 20B-20E. In addition or alternatively, the bleed back lumen 1152 in the handle device 1114 may be a groove (not shown) extending along the lumen 1140 between the proximal and distal ends 1134, 1136 of the handle device 1114. The groove(s) may define a substantially enclosed passage when the apparatus 1110 is received over an introducer sheath 1116 or other elongate member.

The apparatus 1110 may be used in conjunction with an introducer sheath 1116 or other elongate member, having a proximal end 1144 and a distal end 1146. The sheath 1116 may include a tapered and/or substantially atraumatic distal end 1146 having a size for insertion through a puncture into a body lumen 90. The sheath 1116 may include a lumen 1150 that extends between the proximal and distal ends 1144, 1146, the lumen 1150 having a size to accommodate insertion of one or more devices therethrough. The sheath 1116 may include a seal (not shown), e.g., in the lumen 1150 adjacent the proximal end 1144 to substantially seal the lumen 1150, yet accommodate devices (not shown) therethrough.

The apparatus 1110 may be attachable to the sheath 1116 at any time during a procedure, e.g., such that the plug member 1112 and handle device 1114 may slide along the sheath 1116. Alternatively, the apparatus 1110 may be substantially permanently, but slidably, attached to the sheath 1116.

With particular reference to FIG. 20A, initially, the sheath 1116 may be introduced into a puncture or other passage 92 communicating with a blood vessel or other body

lumen 90. The distal end 1146 may be introduced over a guidewire, a trocar, and/or a dilator (all not shown) until the distal end 1146 is disposed in or adjacent to the vessel 90, as is well known to those skilled in the art. One or more instruments or devices (not shown) may be advanced through the lumen 1150 into the vessel 90 to perform a

- 5 procedure at a location within the patient's body accessed by the vessel 90. For example, an endovascular procedure may be performed within a patient's vasculature, such as angioplasty, stenting, atherectomy, and the like.

- As shown in FIG. 20B, upon completing the procedure, any devices may be removed from the lumen 1150, and the plug member 1112 may be delivered into the  
10 passage 92 using the apparatus 1110. With the apparatus 1110 assembled, as shown, the apparatus 110 may be introduced into the passage 92 over the sheath 1116, i.e., by inserting the proximal end 1144 of the sheath 1116 into the lumen 1124 in the plug member 1112 and through the lumen 1140 in the handle device 1114.

- For example, the distal end 1122 of the plug member 1112 may be inserted into the  
15 passage 92 until the thread pattern 1118 begins to engage tissue 96 surrounding the passage 92. Then, as best seen in FIG. 20C, the handle device 1114 may be rotated in a first direction (indicated by exemplary arrow) to thread the plug member 1112 into the passage 92 over the sheath 1114. Consequently, the outer surface 1130 and/or thread pattern 1118 of the plug member 1112 may substantially engage tissue 96 surrounding the  
20 passage 92, thereby substantially sealing the passage 92 from fluids, such as blood, within the vessel 90.

- Turning to FIG. 20C, as the plug member 1112 is advanced, the distal end 1122 of the plug member 1112 may eventually pass through the wall 98 of the vessel 90, whereupon the bleed back port 1154 may become exposed to fluid, i.e., blood, within the  
25 vessel 90. Because of internal blood pressure, the fluid enters the bleed back port 1154, passes through the bleed back lumen 1152, and exits the outlet port 1156 (as represented by drops 1158), thereby providing a visual indication that the vessel 90 has been reached.

- As shown in FIG. 20D, the apparatus 1110 may be counter-rotated to withdraw the plug member 1112 away from the wall 98 of the vessel 90. For example, bleed back may  
30 occur when the plug member 1112 is within or in close proximity to the vessel 90, as shown in FIG. 20C. Rotation of the apparatus 1110 may then be reversed, i.e., in a second direction opposite the first direction (indicated by exemplary arrow), to withdraw the plug

member 1112 a predetermined distance relative to the vessel 90, as shown in FIG. 20D. Because of the known pitch of the thread pattern 1118, the distance that the plug member 1112 is moved relative to the vessel 90 may be related directly to the number of rotations and/or partial rotations that the apparatus 1110 is counter-rotated.

- 5        Once the desired deployment location is attained, the sheath 1116 may be removed, as shown in FIG. 20E. Alternatively, the sheath 1116 may be withdrawn earlier, e.g., when the distal end 1122 of the plug member 1112 is advanced into the vessel 90, or even earlier. As shown, the sealing member 1132 may expand to substantially seal the lumen 1124 in the plug member 1112, similar to the embodiments described above. For
- 10       example, the sealing member 1132 may automatically expand when exposed to fluid, e.g., passing through the lumen 1124. Alternatively, the sealing member 1132 may be expanded to substantially seal the lumen 11124, either by an actuator or by compression of the sealing member 1132 (not shown), similar to the embodiments described above.

- 15       If desired, the bleed back port 1154, e.g., if a separate lumen (not shown) from the lumen 1124, may also include a sealing member (also not shown) for substantially sealing the bleed back port 1154 from fluid flow therethrough, similar to the sealing members described above.

- 20       When the plug member 12 is disposed at a desired location within the passage 92 and/or once hemostasis is obtained, the plug member 1112 may be released from the handle device 1114. The handle device 1114 (and sheath 1116 if still within the passage 92) may be withdrawn from the passage 92. As shown in FIG. 20F, the plug member 1112 may remain in place to substantially seal the passage 92, e.g., until the plug member 1112 is absorbed by the patient's body. Alternatively, the plug member 1112 may be retrieved once the tissue between the plug member 1112 and the vessel 90 has
- 25       substantially healed, as described above.

- 30       While the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the appended claims.

- 45 -

CLAIMS:

1. An apparatus for sealing a passage through tissue, comprising:  
an elongate shaft having a proximal end and a distal end; and  
a plug member disposed on the distal end of the elongate shaft, the plug member  
5 comprising a helical thread on its outer surface, the elongate shaft having a cross-section  
that is substantially smaller than a cross-section of the plug member.
2. The apparatus of claim 1, wherein the plug member is at least partially  
tapered at its distal end.
- 10 3. The apparatus of claim 1, wherein the plug member comprises a cavity in  
its distal end.
4. The apparatus of claim 3, further comprising at least one of a hemostasis-  
15 promoting material and an infection-resistant material is disposed in the cavity.
5. The apparatus of claim 4, wherein the material comprises intestinal  
submucosa.
- 20 6. The apparatus of claim 1, further comprising at least one of a hemostasis-  
promoting material and an infection-resistant material secured to a distal end of the plug  
member.
7. The apparatus of claim 1, wherein the plug member is releasable from the  
25 elongate shaft.
8. The apparatus of claim 7, wherein the elongate shaft comprises an actuator  
for releasing the plug member from the distal end of the elongate shaft.
- 30 9. The apparatus of claim 7, further comprising cooperating connectors on the  
distal end of the elongate shaft and on the plug member for releasably securing the plug  
member to the distal end of the elongate shaft.

- 46 -

10. The apparatus of claim 7, wherein the plug member comprises an interior cavity, and wherein the elongate shaft comprises an engagement element extending from the distal end thereof for insertion into the cavity, the engagement element being  
5 expandable and collapsible for engaging and disengaging an interior wall of the plug member, thereby selectively securing the plug member to and releasing the plug member from the distal end of the elongate shaft, respectively.
11. The apparatus of claim 10, wherein the engagement element comprises a  
10 mechanically expandable frame.
12. The apparatus of claim 10, wherein the engagement element comprises an inflatable member.
13. The apparatus of claim 10, wherein the plug member is sufficiently rigid  
15 such that the plug member is substantially self-supporting when the engagement member is collapsed.
14. The apparatus of claim 7, wherein the plug member comprises  
20 bioabsorbable material.
15. The apparatus of claim 1, wherein the plug member is substantially permanently attached to the distal end of the elongate shaft.
16. The apparatus of claim 1, further comprising a lumen extending from the  
25 proximal end of the elongate shaft through the plug member, and a seal for selectively sealing the lumen.
17. The apparatus of claim 16, wherein the seal is disposed on the proximal end  
30 of the elongate shaft.



- 47 -

18. An apparatus for sealing a passage through tissue, comprising:  
an elongate member having a proximal end, a distal end, and a lumen extending  
between the proximal and distal ends; and  
a plug member disposed on the distal end of the elongate member, the plug  
5 member comprising a helical thread on its outer surface, the plug member comprising a  
distal port therein in communication with the lumen, the plug member having a cross-  
section larger than a cross-section of the elongate member.
19. The apparatus of claim 18, wherein the plug member comprises a passage  
10 therein extending between the distal port and the lumen.
20. The apparatus of claim 19, further comprising a sealing member disposed  
in the passage for substantially sealing the passage from fluid flow therethrough.
- 15 21. The apparatus of claim 20, wherein the sealing member comprises a  
material that is expandable when exposed to fluid for substantially sealing the passage.
22. The apparatus of claim 20, wherein the sealing member is biased towards a  
first configuration for substantially sealing the passage from fluid flow therethrough, and  
20 is movable to a second configuration for accommodating introduction of one or more  
devices through the passage.
23. The apparatus of claim 20, wherein the sealing member comprises a valve.
- 25 24. The apparatus of claim 20, wherein the lumen includes a tapered portion  
reducing in cross-section, and wherein the sealing member comprises a generally annular-  
shaped member disposed adjacent a wide end of the tapered portion of the lumen, the  
annular-shaped being movable into the tapered portion for substantially sealing the lumen.

- 48 -

25. The apparatus of claim 24, further comprising a activation element coupled to the elongate member, the activation element extending into the lumen of the plug member for moving the sealing member into the tapered portion for substantially sealing the lumen.
- 5
26. The apparatus of claim 19, further comprising an elongate member insertable through the lumen such that a distal end of the elongate member is disposed beyond the distal end of the plug member.
- 10
27. The apparatus of claim 26, wherein the distal end of the elongate member comprises a location indicator for identifying when the distal end of the plug member is disposed adjacent a body lumen.
28. The apparatus of claim 27, wherein the elongate member comprises a
- 15 tubular member including a bleed back lumen, and wherein the location indicator comprises a bleed back port on the distal end of the tubular member, the bleed back port being in communication with the bleed back lumen.
29. The apparatus of claim 27, wherein the location identifier comprises an
- 20 expandable member, the expandable member being expandable when the distal end is disposed within a body lumen for providing tactile feedback of a location of the distal end of the plug member with respect to the body lumen.
30. The apparatus of claim 26, wherein the elongate member comprises an
- 25 obturator including a substantially atraumatic distal tip.
31. The apparatus of claim 26, further comprising a valve in the passage for substantially sealing the passage yet accommodating insertion of the elongate member therethrough.
- 30
32. The apparatus of claim 18, wherein the plug member is releasable from the elongate member.

33. The apparatus of claim 32, wherein the elongate member comprises an actuator for releasing the plug member from the distal end of the elongate member.

5 34. The apparatus of claim 32, further comprising cooperating connectors on the distal end of the elongate member and on the plug member for releasably securing the plug member to the distal end of the elongate member.

35. The apparatus of claim 32, wherein the plug member comprises an interior  
10 cavity, and wherein the elongate member comprises an engagement element extending from the distal end thereof for insertion into the cavity, the engagement element being expandable and collapsible for engaging and disengaging an interior wall of the plug member, thereby selectively securing the plug member to and releasing the plug member from the distal end of the elongate member, respectively.

15

36. The apparatus of claim 32, wherein the plug member comprises bioabsorbable material.

37. An apparatus for sealing a passage through tissue, comprising:  
20 an elongate member comprising proximal and distal portions, and a groove in an outer wall of the elongate member extending between the proximal and distal portions;  
a carrier member comprising proximal and distal ends, and a first lumen extending between the proximal and distal ends; and  
a plug member on the distal end of the carrier member, the plug member  
25 comprising a second lumen extending therethrough that communicates with the first lumen,

wherein the elongate member is slidable into the first and second lumens such that edges of the groove substantially engage walls of the first and second lumens to define a bleed back lumen.

30

38. The apparatus of claim 38, wherein the plug member comprises a helical thread on its outer surface.

- 50 -

39. The apparatus of claim 38, wherein the plug member has a cross-section larger than a cross-section of the carrier member.

5           40. The apparatus of claim 37, further comprising a sealing member disposed in the second lumen for substantially sealing the second lumen from fluid flow therethrough.

41. The apparatus of claim 40, wherein the sealing member comprises a  
10 material that is expandable when exposed to fluid.

42. The apparatus of claim 40, wherein the sealing member is biased towards a first configuration for substantially sealing the second lumen from fluid flow therethrough, and is movable to a second configuration for accommodating introduction of one or more  
15 devices through the second lumen.

43. The apparatus of claim 40, wherein the sealing member comprises a valve.

44. The apparatus of claim 40, wherein the sealing member comprises a  
20 generally annular-shaped member disposed within the second lumen, the apparatus further comprising an activation element coupled to the carrier member, the activation element being movable within the second lumen for deforming the annular-shaped member to substantially seal the second lumen.

25           45. The apparatus of claim 44, wherein the second lumen comprises a tapered portion reducing in cross-section, and wherein the annular-shaped member is movable into the tapered portion by the activation element for substantially sealing the second lumen.

46. The apparatus of claim 44, wherein a distal end of the annular-shaped  
30 member is secured from distal movement, and wherein the activation element is configured for compressing a proximal end of the annular-shaped member towards the distal end thereof to wedge the annular-shaped member into the second lumen.

47. The apparatus of claim 37, wherein the elongate member comprises a tubular member.
- 5 48. The apparatus of claim 47, wherein the tubular member comprises a guidewire lumen extending between the proximal and distal ends for receiving a guidewire therethrough.
49. The apparatus of claim 37, wherein the elongate member comprises a plurality of grooves extending between the proximal and distal portions.
- 10 50. The apparatus of claim 37, wherein the plug member is releasable from the carrier member.
51. The apparatus of claim 50, wherein the carrier member comprises an actuator for releasing the plug member from the distal end of the carrier member.
- 15 52. The apparatus of claim 51, further comprising cooperating connectors on the distal end of the carrier member and on the plug member for releasably securing the plug member to the distal end of the carrier member.
- 20 53. The apparatus of claim 50, wherein the plug member comprises an interior cavity, and wherein the carrier member comprises an engagement element extending from the distal end thereof for insertion into the cavity, the engagement element being expandable and collapsible for engaging and disengaging an interior wall of the plug member, thereby selectively securing the plug member to and releasing the plug member from the distal end of the carrier member, respectively.
- 25 54. The apparatus of claim 50, wherein the plug member comprises bioabsorbable material.
- 30

- 52 -

55. The apparatus of claim 50, wherein rotation of the plug member is coupled to rotation of the carrier member until the plug member is released from the carrier member.

5 56. An apparatus for sealing a passage through tissue, comprising:  
an elongate shaft having a proximal end and a distal end; and  
a plug member substantially permanently attached to the distal end of the elongate shaft, the plug member comprising a helical thread on its outer surface.

10 57. The apparatus of claim 56, wherein the plug member comprises a cavity in its distal end.

58. The apparatus of claim 57, further comprising at least one of a hemostasis-promoting material and an infection-resistant material disposed in the cavity.

15 59. The apparatus of claim 56, further comprising at least one of a hemostasis-promoting material and an infection-resistant material secured to a distal end of the plug member.

20 60. The apparatus of claim 56, further comprising a lumen extending from the proximal end of the elongate shaft through the plug member, and a seal for selectively sealing the lumen.

25 61. A device for sealing a passage through tissue, comprising a plug member formed from a bioabsorbable material, the plug member comprising a proximal end, a substantially closed distal end, and a helical thread on an outer cylindrical surface extending at least partially between the proximal and distal ends.

30 62. The device of claim 61, further comprising a connector on the proximal end for detachably securing the plug member to a delivery apparatus.

- 53 -

63. The device of claim 61, wherein the body further comprises an internal cavity communicating with an opening in the proximal end.

64. The device of claim 61, further comprising:  
5 a lumen extending between the proximal end and a distal inlet port; and  
a sealing member disposed within the lumen that is expandable across the lumen for substantially sealing the lumen from fluid flow therethrough.

65. The device of claim 64, wherein the sealing member comprises a material  
10 that is expandable when exposed to fluid to substantially seal the lumen.

66. The device of claim 64, wherein the sealing member comprises an annular-shaped member.

66. The device of claim 64, wherein the sealing member comprises a  
15 bioabsorbable material.

67. The device of claim 64, further comprising an elongate shaft extending  
20 from the proximal end of the body.

68. A device for sealing a passage through tissue, comprising:  
a bioabsorbable body comprising a proximal end, a distal end, and a helical thread  
on an outer surface extending at least partially between the proximal and distal ends, the  
body comprising a lumen extending between a proximal port and a distal port, the lumen  
25 comprising a tapered portion that tapers in cross-section; and  
a sealing member comprising a generally annular-shaped member disposed  
adjacent a wide end of the tapered portion of the lumen, the sealing member being  
movable into the tapered portion for substantially sealing the lumen from fluid flow  
therethrough.

69. The device of claim 68, wherein the sealing member comprises a material  
30 that is expandable when exposed to fluid to substantially seal the lumen.

- 54 -

70. The device of claim 68, wherein the sealing member comprises a flexible material that may be wedged into the tapered portion.

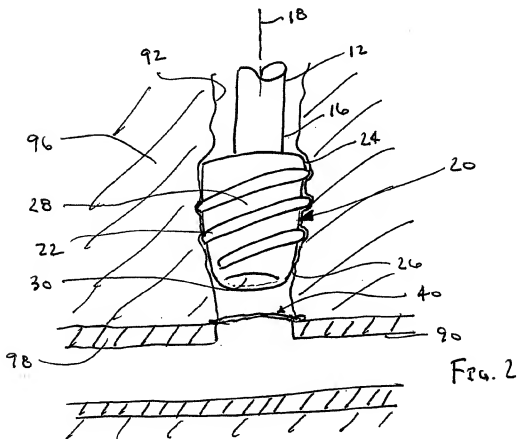
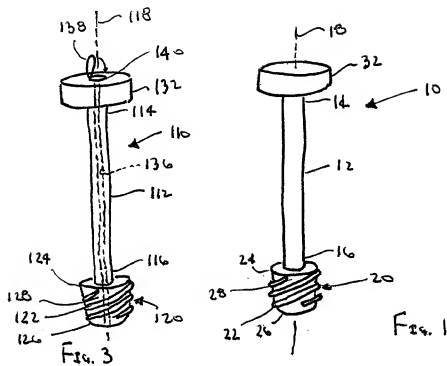
5           71. The device of claim 68, wherein the sealing member comprises a bioabsorbable material.

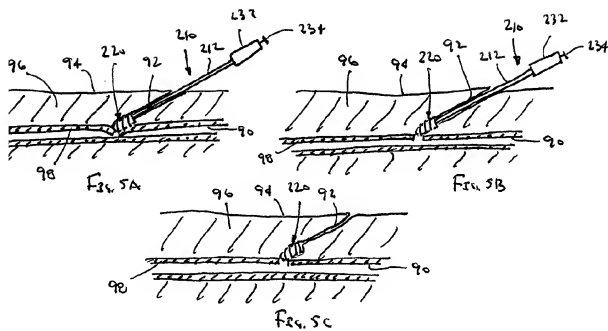
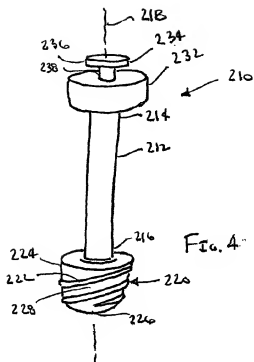
72. The device of claim 68, further comprising a connector on the proximal end of the body for detachably securing the body to a delivery device.

10

73. The device of claim 68, further comprising an elongate shaft extending from the proximal end of the body.







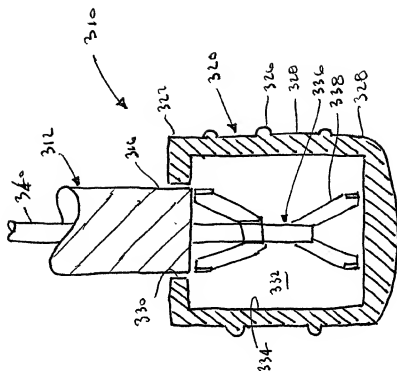


Fig. 6B

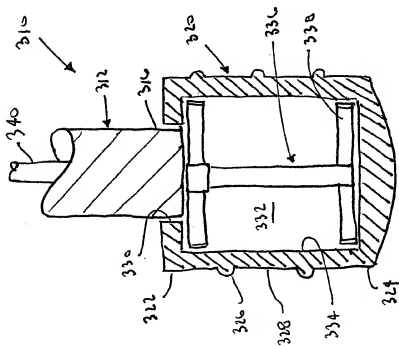


Fig. 6A

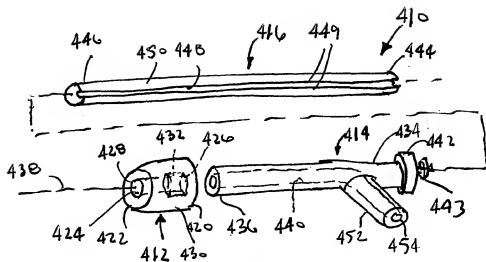


FIG. 7A

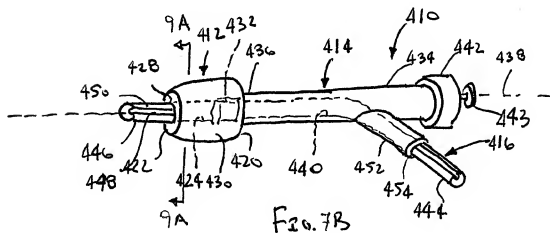
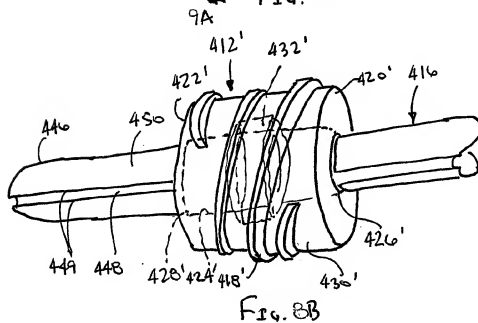
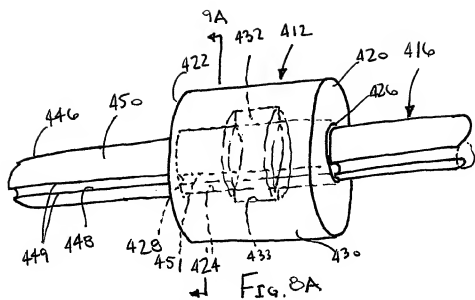
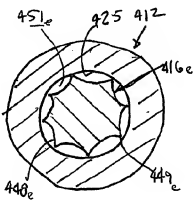
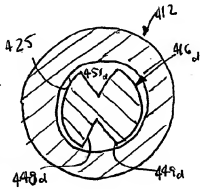
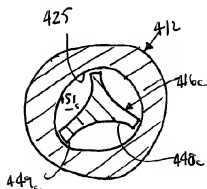
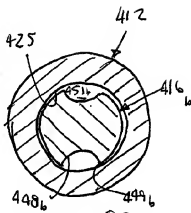
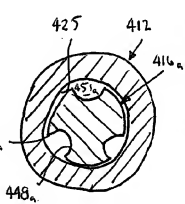
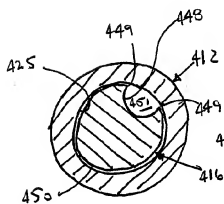
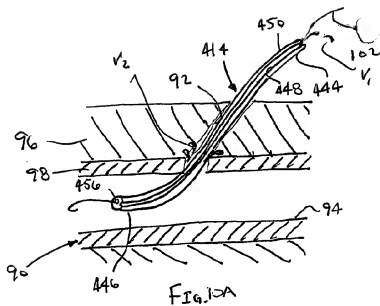
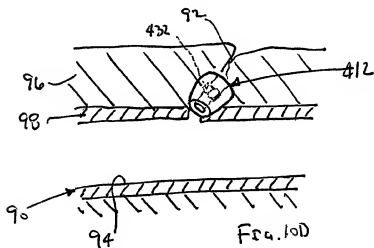
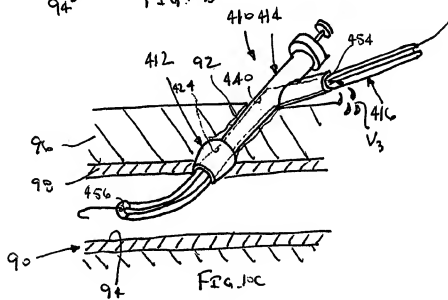
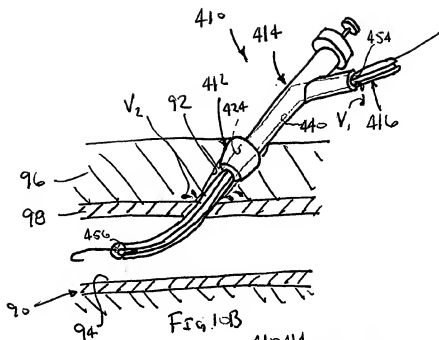
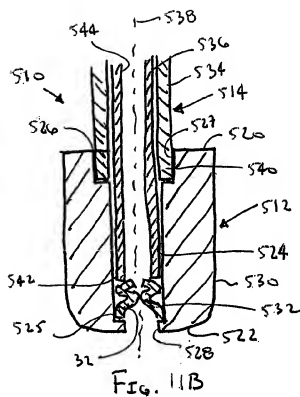
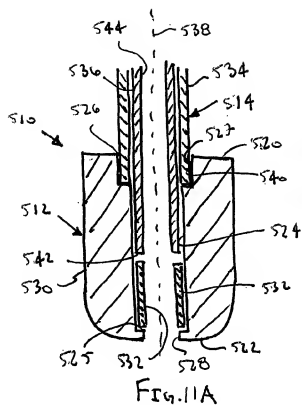


FIG. 7B











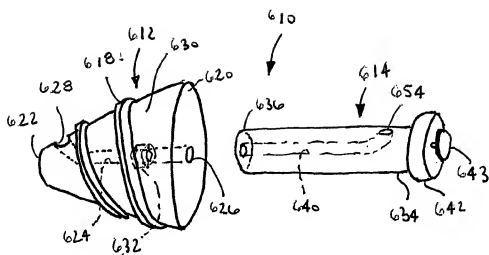


FIG. 12

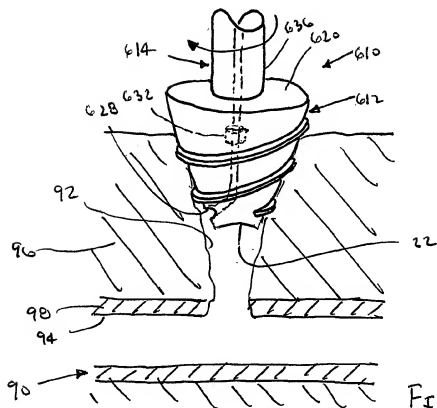
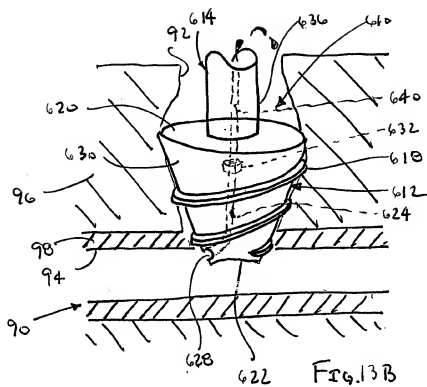


FIG. 13A



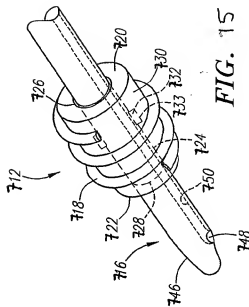
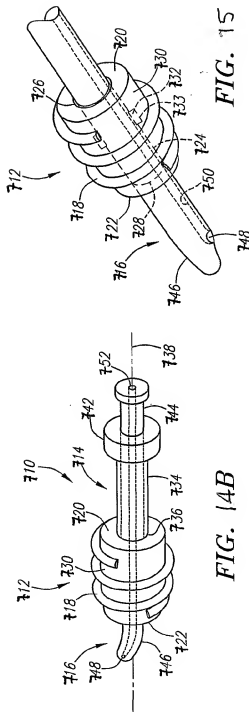
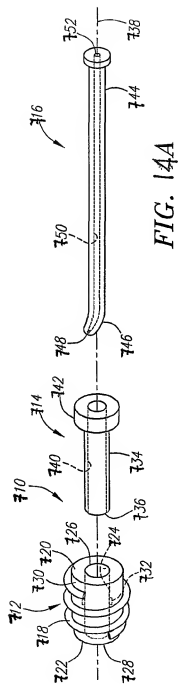


FIG. 16A

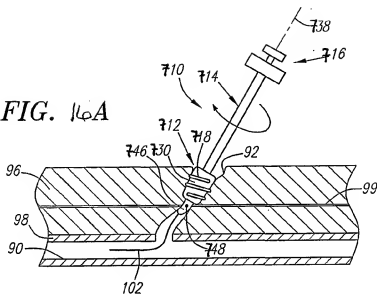


FIG. 16B

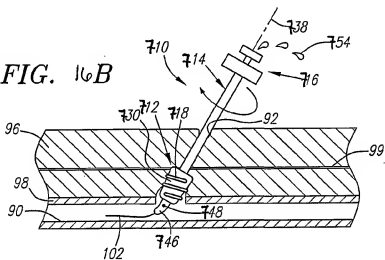
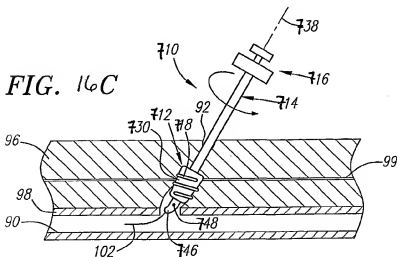


FIG. 16C



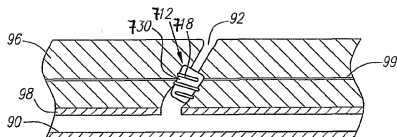


FIG. 16D

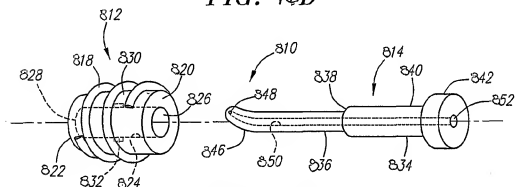


FIG. 17A

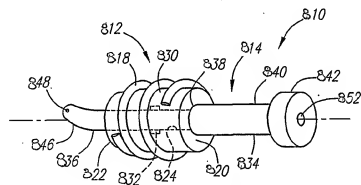


FIG. 17B

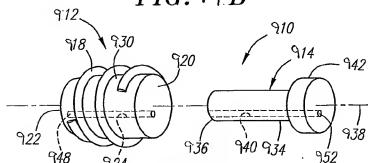


FIG. 18

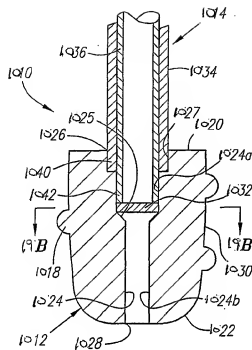


FIG. 19 A

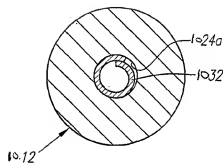


FIG. 19 B

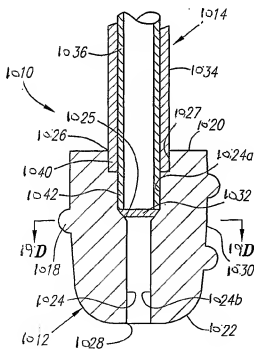


FIG. 19 C

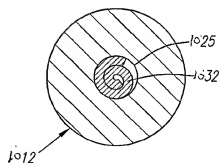


FIG. 19 D

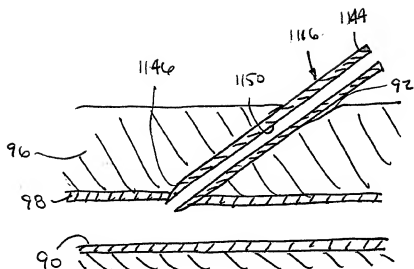


FIG. 20A

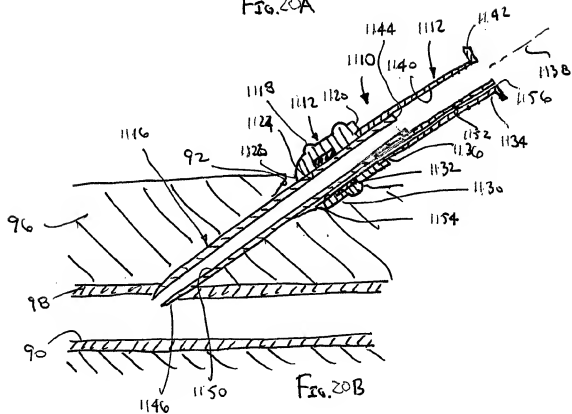
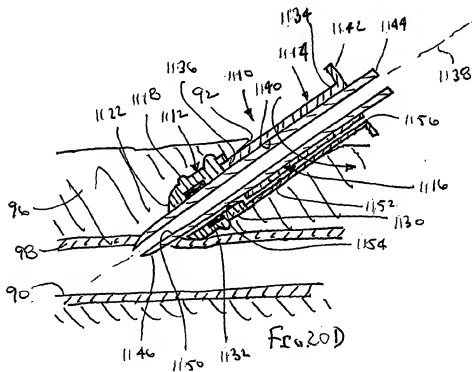
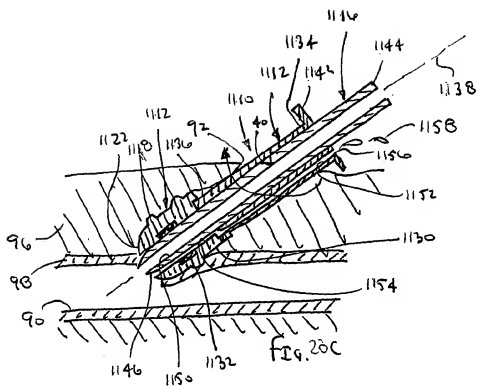
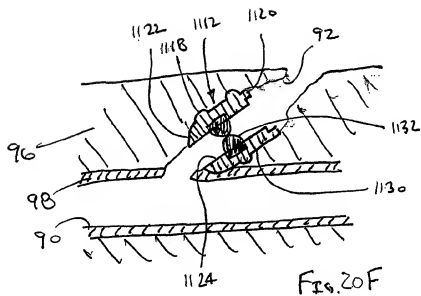
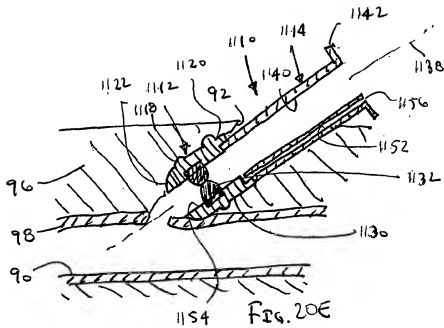


Fig. 20B







## INTERNATIONAL SEARCH REPORT

International Application No.  
PCT/US 01/48843

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 032 125 A (BRUMFIELD DAVID L ET AL) 16 July 1991 (1991-07-16) column 3, line 66 - column 4, line 20; figure 5	1,2,11, 56
Y	---	18,19
Y	US 5 425 757 A (TIEFENBRUN JONATHAN ET AL) 20 June 1995 (1995-06-20) column 4, line 62 - line 64; figure 11	18,19
A	US 5 645 565 A (RUDD RAY G ET AL) 8 July 1997 (1997-07-08) column 3, line 16 - line 51; figure 1	1,2,18, 56,61,69
A	US 6 016 806 A (WEBB NICHOLAS J) 25 January 2000 (2000-01-25) abstract; figure 2	1,2,18, 56
	--- -/-	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

\*A\* document defining the general state of the art which is not considered to be of particular relevance

\*E\* earlier document but published on or after the international filing date

\*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

\*O\* document referring to an oral disclosure, use, exhibition or other means

\*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*Z\* document member of the same patent family

Date of the actual completion of the international search

6 August 2002

Date of mailing of the international search report

13/08/2002

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2340, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Ducreau, F

## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 01/48843

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 571 181 A (LI SHU-TUNG) 5 November 1996 (1996-11-05) column 2, line 53 - line 64; figure 1 -----	1, 18, 37, 56, 61, 69
A	US 5 061 274 A (KENSEY KENNETH) 29 October 1991 (1991-10-29) abstract; figures 5-8 -----	37

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/48843

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5032125	A	16-07-1991	AT 131371 T	15-12-1995
			AU 649644 B2	02-06-1994
			AU 7025491 A	08-08-1991
			CA 2035661 A1	07-08-1991
			DE 69115302 D1	25-01-1996
			DE 69115302 T2	15-05-1996
			DK 441577 T3	04-03-1996
			EP 0441577 A2	14-08-1991
			ES 2082922 T3	01-04-1996
			JP 3009232 B2	14-02-2000
			JP 4215751 A	06-08-1992
			ZA 9100835 A	29-01-1992
US 5425757	A	20-06-1995	NONE	
US 5645565	A	08-07-1997	NONE	
US 6016806	A	25-01-2000	EP 0971657 A1	19-01-2000
			JP 2001520550 T	30-10-2001
			WO 9842282 A1	01-10-1998
			US 6041785 A	28-03-2000
			US 6082362 A	04-07-2000
US 5571181	A	05-11-1996	US 5326350 A	05-07-1994
			US 6350274 B1	26-02-2002
			WO 9525481 A1	28-09-1995
US 5061274	A	29-10-1991	CA 2122041 A1	29-04-1993
			EP 0609212 A1	10-08-1994
			WO 9307813 A1	29-04-1993
			US 5192302 A	09-03-1993
			AU 3056692 A	07-06-1993
			EP 0619718 A1	19-10-1994
			JP 7503381 T	13-04-1995
			WO 9308743 A1	13-05-1993